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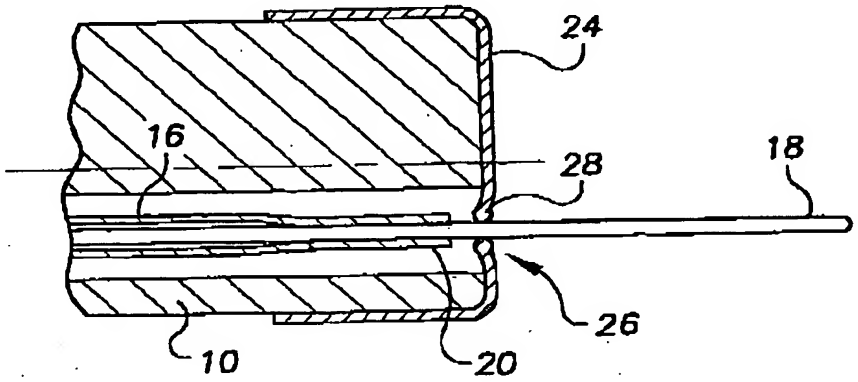

(57) Abstract: Provided is an endoscopic tool restraint for restraining longitudinal movement of an endoscopic tool with respect to a distal port of an endoscope channel through which the tool can be distally advanced and proximally retracted longitudinally. The restraint includes at least one restraining member disposed at least as distally as the endoscope channel distal port. The restraining member is positioned in spatial correspondence with the distal port to engage the tool when a distal end of the tool extends distally beyond the restraining member. This provides the ability to maintain the distal end of an endoscopic tool such as a guidewire in-position with respect to the distal port of the endoscope, enabling, e.g., a working catheter to be withdrawn over the guidewire, through the endoscope, from the site while the guidewire remains in its intended position at the site.

WO 01/58360 A2

ENDOSCOPIC TOOL RESTRAINT

BACKGROUND OF THE INVENTION

This invention relates to medical catheterization techniques, and more particularly relates to endoscopes and to endoscopic tools such as guidewires used during catheter exchange procedures.

In a typical catheterization procedure carried out for, e.g., gastrointestinal or cardiovascular diagnosis or treatment, an endoscope or guide catheter is first introduced into an internal body lumen and its distal port then advanced to the vicinity of a diagnostic or treatment procedure site. A working catheter to be employed in the course of the procedure is then guided to the procedure site through the working channel of the, say, endoscope. Typically, the working catheter, being of a relatively flexible material, is first partially advanced over a more maneuverable endoscopic tool such as a guidewire and the assembly then advanced through the working channel of the endoscope to the procedure site. Here the advancing, i.e., distal, tip of the guidewire extends beyond the distal end of the working catheter. This enables a physician to successfully manipulate the more maneuverable guidewire through the endoscope to the intended procedure site and then to fully advance the working catheter over the guidewire to the site. Alternatively, the guidewire is alone advanced through the endoscope to the site and then the working catheter is guided over the guidewire to the site. In a typical procedure configuration, the guidewire distal tip is positioned beyond the distal port of the endoscope and beyond the procedure site and the distal end of the working catheter is advanced beyond the distal port of the endoscope to the procedure site. Once positioned, a procedure step employing the working catheter can be carried out.

Because a given working catheter typically is customized for a single activity, such as arterial balloon dilation or tissue biopsy, it is frequently necessary to employ several different working catheters during a diagnostic or treatment procedure. As a result of this customization, multiple working

catheters are commonly needed to accomplish various steps of a diagnostic or treatment procedure.

During a procedure involving the use of multiple working catheters, a first working catheter is guided to the procedure site over a guidewire and through an endoscope in the manner described above, and once the procedure step employing that catheter is complete, the catheter is withdrawn from the site over the guidewire and out the endoscope, which is conventionally maintained in the body lumen throughout the procedure. The guidewire is preferably maintained in-position in the endoscope at the procedure site during withdrawal of the working catheter from the site. A next working catheter to be employed is then advanced over the in-position guidewire, through the endoscope, to the procedure site, to carry out the next step of the procedure. This working catheter advance-withdrawal-advance scenario may need to be carried out many times during the course of a procedure to accomplish all of the procedure steps, and typically is to be accomplished with minimal delay, thus the general use of the description "rapid catheter exchange" for this technique. Maintenance of the guidewire in-position at the procedure site facilitates speed of catheter placement while ensuring that each catheter employed during the procedure is directed to the precise site location.

Due to the typically small clearance between a guidewire and the internal walls of a working catheter threaded on the guidewire, withdrawal of a catheter from the procedure site can tend to also frictionally pull the guidewire back from the site. Bends in the endoscope through which the catheter is withdrawn and other factors can also add to an undesirable pulling back of the guidewire from the procedure site as a catheter is withdrawn. This can result in partial or complete withdrawal of the guidewire from the procedure site and even out of the endoscope, requiring reintroduction of a guidewire to the procedure site to enable further catheter introduction. Guidewire contamination, misplacement at the procedure site, and delays in procedure can result.

SUMMARY OF THE INVENTION

The present invention provides the ability to maintain the distal end of a guiding tool such as a guidewire in-position with respect to an endoscope distal port at an internal procedural site, enabling, e.g., a working catheter to be withdrawn over the guidewire, through the endoscope, from the site. This is accomplished with an endoscopic tool restraint provided by the invention for restraining longitudinal movement of an endoscopic tool with respect to a distal port of an endoscope channel through which the tool can be distally advanced and proximally retracted longitudinally. The restraint includes at least one restraining member disposed at least as distally as the endoscope channel distal port. The restraining member is positioned in spatial correspondence with the distal port to engage the tool when a distal end of the tool extends distally beyond the restraining member.

The restraining member can be configured with a contact surface for making direct contact with the endoscopic tool at least as distally as the endoscope channel distal port. This configuration is particularly well-suited for a scenario in which a catheter is located in the endoscope channel, over the tool, when a distal end of the catheter is proximate the contact surface and a distal end of the tool extends distally beyond the contact surface. The contact surface can be oriented with respect to the distal port of the endoscope to exert against the tool, when in contact with it, sufficient contact force to restrain longitudinal movement of the tool when a catheter is longitudinally moved over the tool within the endoscope channel and a distal end of the catheter is proximate the restraining member.

The endoscopic tool restraint can be employed with a wide range of tools, including, e.g., a guiding tool, such as a guidewire. The adaptability of the restraint configuration enables customization of the restraint for a given application, endoscopic tool, and endoscope configuration, including side-view endoscope configurations and multi-channel endoscope configurations. For example, the restraining member can be connected to an exterior wall of the endoscope by a restraining connector, but such is not required. The

restraining member can be provided as a plurality of restraining members which are each positioned in spatial correspondence with the distal port to engage the tool when a distal end of the tool extends distally beyond the restraining members.

A restoring member can be connected between the restraining member and the endoscope. This restoring member, provided as, e.g., a spring element, can be connected in a condition that opposes engagement of the tool by the restraining member or in a condition that effects engagement of the tool by the restraining member.

A restraining member activator or de-activator can be connected to the restraining member, and extended proximate a proximal port of the endoscope channel. Such an activator or de-activator can be provided in a condition, when actuated at a proximal end, that effects or opposes, respectively, engagement of the tool by the restraining member. A pull cord, positioned within the endoscope channel or positioned exterior to the endoscope channel, can be employed as such a restraining member activator or de-activator.

The restraining member can be disposed at the distal port of the endoscope channel and/or distally beyond the channel distal port. If it is disposed distally beyond the port, then preferably a restraining member connector is connected between the restraining member and an exterior wall of the endoscope.

In an example embodiment provided by the invention, the restraining member is a gripper lip provided in a restraining cap over the distal port of the endoscope channel. The gripper lip can include a circumferential lip passage in which is provided a pull cord that extends proximally from the lip passage to a proximal end of the endoscope for activation of the gripper lip to engage the endoscopic tool when the pull cord is proximally actuated.

In a further embodiment, the restraining member is a gripper tube provided in a restraining cap over the distal port of the endoscope. The gripper tube can extend distally beyond the endoscope channel distal port or proximally, interior to the endoscope channel. The tube can include a

circumferential tube passage in which is provided a pull cord that extends proximally from the tube passage to a proximal end of the endoscope for activation of the gripper tube to engage the endoscopic tool. The tube can further be adapted with a restoring spring in the gripper tube that is provided in a condition that biases the gripper tube to effect engagement of the endoscopic tool when the pull cord is proximally actuated.

In a further embodiment, the restraining member is a restraining wedge that is disposed distally to the endoscope channel distal port. The wedge is connected to a pull cord that extends proximally through the endoscope channel to a proximal end of the endoscope. The wedge is sized to engage the endoscopic tool when the pull cord is proximally activated. A restoring band can be connected between the wedge and an exterior wall of the endoscope. A plurality of restraining wedges can be provided, each disposed distally to the ndoscope channel distal port and connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope. Here the restraining wedges are sized to engage the endoscopic tool when the pull cord is proximally activated.

In an alternative embodiment, the restraining member is provided as two restraining cams that are each disposed distally to the endoscope channel distal port. The cams are connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope. The restraining cams are sized to engage the endoscopic tool between them when the pull cord is proximally activated. A bias spring can be connected to each of the cams to bias them apart. Additionally, each cam can include a magnetic material portion that attracts the two cams toward the endoscopic tool. In a similar configuration, the restraining member can be provided as a pair of grippers, where each gripper in the pair includes a distal grip and a proximal grip. Both distal and proximal grips are disposed distally to the endoscope channel distal port and both grippers in the pair are connected to a spring element to bias the distal grips toward each other.

In a further embodiment, the restraining member is a plate hinged at one edge at the distal port of the endoscope channel. The plate includes a passage that can be aligned with the distal port by rotation of the plate. The plate is connected by a spring to an exterior wall of the endoscope at a plate edge that is opposite the hinged plate edge. The spring is biased to maintain the plate in a position that effects engagement of the endoscopic tool by a wall of the plate passage. The plate is connected to a pull cord that extends proximally though the endoscope channel to a proximal end of the endoscope for opposing engagement of the tool when the cord is proximally actuated.

The endoscopic tool restraint of the invention can further be provided as a restraining bushing that is disposed distally to the distal port of the endoscope. The bushing is elastically connected to a bushing housing that accommodates rotation of the bushing. The bushing includes a passage that can be aligned with the endoscope distal port by the rotation of the bushing. The bushing is connected to a pull cord that extends proximally through the endoscope channel to a proximal end of the endoscope for rotating the bushing when the cord is proximally actuated.

The endoscopic tool restraint of the invention can further be provided as an elastically deformable gripper sidewall that is connected to a restraining cap over the distal port of the endoscope. The gripper sidewall includes a pivot portion at which the sidewall can pivot proximally toward the endoscope channel distal port. A pull cord is connected to the gripper sidewall and extends proximally through the endoscope channel to a proximal end of the endoscope for rotating the sidewall when the cord is proximally actuated. A contact wall can be provided in the restraining cap opposite the gripper sidewall and extending for a length sufficient to enable engagement of the endoscopic tool between the gripper sidewall and the contact wall when the gripper sidewall is rotated.

A wide range of endoscope configurations and endoscopic procedures are accommodated by the restraint configuration of the invention. With regard to the use of endoscopic tools such as guidewires, the invention is particularly

well-suited to enable rapid catheter exchange without the need for overly-long guidewires, exchange guidewires, or guidewire extensions. Other features and advantages of the invention will be apparent from the following description and accompanying figures, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A-B are partial cross-sectional views of an endoscope, having a guidewire restraining cap provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, and in a condition where the cap is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Fig. 1C is an end view of an endoscope distal port, looking proximally, including the restraining cap of Figs. 1A-B provided with optics and fluidic ports;

Fig. 1D is a partial cross-sectional view of an adaptation of the guidewire restraining cap of Figs. 1A-B provided in accordance with the invention;

Figs. 2A-C are partial cross-sectional views of an endoscope, having a guidewire restraining cap with endoscope-internal pull cord-actuated gripper lip provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper lip is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 2D-E are each end views, looking proximally, of an endoscope including the restraining cap of Figs. 2A-C here adapted such that the pull cord-actuated gripper lip is composed of discontinuous segments; in a condition where the gripper lip is not actuated, and in a condition where the gripper lip is restraining the guidewire, respectively;

Figs. 3A-C are partial cross-sectional views of an endoscope, having a guidewire restraining cap with endoscope-external pull cord-actuated gripper lip provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper lip is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 4A-C are partial cross-sectional views of an endoscope, having a guidewire restraining cap with pull cord-actuated external gripper tube provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper tube is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 5A-C are partial cross-sectional views of an endoscope, having a guidewire restraining cap with pull cord-actuated internal gripper tube provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper tube is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 6A-C are partial cross-sectional views of an endoscope, having a guidewire restraining piston-gripper tube provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper tube is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 7A-C are partial cross-sectional views of an endoscope, having a pull cord-actuated guidewire restraining piston-gripper tube provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the gripper tube is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 8A-C are partial cross-sectional views of an endoscope, having a pull cord-actuated guidewire restraining wedge provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the wedge is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 9A-C are partial cross-sectional views of an endoscope, having a pull cord-actuated and elastically biased restraining wedge provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the wedge is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 10A-C are partial cross-sectional views of an endoscope, having two pull cord-actuated and elastically biased restraining wedges provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the wedges are restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 11A-B are partial cross-sectional views of an endoscope, having two pull cord-actuated and elastically biased cooperating cams provided by the

invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, and in a condition where the cams are restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 12A-B are partial cross-sectional views of an endoscope, having two elastically biased cooperating grippers provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, and in a condition where the grips are restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 13A-B are partial cross-sectional views of an endoscope, having a pull cord-de-actuated and elastically biased guidewire restraint plate provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, and in a condition where the plate is restraining the guidewire as the catheter is proximally withdrawn, respectively;

Figs. 14A-B are partial cross-sectional views of an endoscope, having a pull cord-de-actuated and elastically biased guidewire restraint bushing provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, and in a condition where the ball is restraining the guidewire as the catheter is proximally withdrawn, respectively; and

Figs. 15A-C are partial cross-sectional views of an endoscope, having a pull cord-actuated gripper tab in a restraining wall provided by the invention at the distal port of the endoscope, in a condition where a catheter and guidewire are distally advanced beyond the distal port of the endoscope, in a condition where the catheter is proximally withdrawn into the endoscope working channel, and in a condition where the pull cord is proximally actuated to rotate the gripper tab for restraining the guidewire as the catheter is proximally withdrawn, respectively.

DETAILED DESCRIPTION OF THE INVENTION

A range of configurations of the endoscopic tool restraint mechanisms of the invention are provided and described below, including both passive, automatic, and actuatable configurations, all of which can be employed with many different tools, e.g., guidewires, needles, and other endoscopic tools. For clarity, the restraint mechanisms of the invention will be described and shown in conjunction with a conventional, solid guidewire. It is to be recognized, however, that the restraint mechanisms of the invention can be employed with, e.g., hollow infusion guidewires that can deliver fluids, as well as other guidewire configurations, with guiding tools in general, and with other elongated endoscopic tools, generally that exhibit stiffness sufficient to render the restraint mechanisms operable in connection with a given procedure employing the tool.

Also for clarity, the restraint configurations will be described in conjunction with an endoscope and a generic working catheter to be deployed internal to the endoscope. But it is to be recognized that the endoscopic tool restraints of the invention can be employed with guiding catheters in general, not just with endoscopes, as well as other guiding catheter-like lumens, and is further not limited to a particular type of working catheter.

Referring to Fig. 1A, diagrammatically illustrating a first restraint configuration in partial cross-section, there is shown the distal end of an endoscope 10 having a working channel 12 that extends the longitudinal length of the endoscope between a proximal port, at which various control and other conventional features can be provided, and a distal port 14. A working catheter 16 is shown advanced over a guidewire 18. Both the catheter and the guidewire are within the endoscope working channel with the distal end 20 of the catheter longitudinally extended beyond the distal port 14 of the endoscope and the guidewire distal tip 22 extended beyond the distal end 20 of the working catheter.

The example endoscope 10 shown in Fig. 1A will be referred to in the following discussion for clarity, but it is to be recognized that the guidewire

restraint of the invention can be configured with alternative endoscope configurations, such as a side-viewing endoscope, in which the distal port of the endoscope is located at a point along the endoscope wall that is proximal of the most distal end of the endoscope, in the conventional configuration.

A guidewire restraining cap 24 is provided at the distal end of the endoscope, with an opening 26 in the cap located in correspondence with the distal port 14 of the working channel 12. The opening preferably consists of a small hole, such as a pinhole. A gripper lip 28 surrounds the opening 26. The restraining cap is formed of an elastic material, such as rubber, thermoplastic elastomer, silicone, polyurethane, or other suitable material, that is characterized by a restoring force that tends to close the gripper lip 28 around the opening 26. The gripper lip can be provided as a molded section or, e.g., as a ring or grommet that is molded in the cap material. The gripper lip and/or the restraining cap can be reinforced using a suitable material such as, e.g., a wire mesh, plastic mesh, or other material.

The restraining cap is attached to the outer wall 30 of the endoscope 10 in a robust manner, e.g., as a frictional attachment, by stretching the cap over the distal port of the endoscope and down the exterior sidewall of endoscope, e.g., a distance of about 0.5 inches. If desired, a lip, rim, or other reinforcement can be provided in the cap at its proximal end, to reinforce its grip on the endoscope wall. Whatever attachment technique is employed, it preferably is sufficiently robust that the cap remains fully attached to the endoscope during advance and withdrawal of the endoscope through an internal body lumen.

Referring also to Fig. 1C, which is a view of the distal port of the endoscope looking proximally, with the restraining cap 24 over the distal port of the endoscope, the restraining cap can be provided with molded or cut-out ports to accommodate use of various endoscope channels other than the working channel. For example, a first port 17 in the cap 24 can be provided to enable use of endoscope optics, a second port 19 can be provided for fluid injection, a third port 20 can be provided for fluid aspiration, and so on, with a

distinct port provided for each channel to be operational during a procedure employing the endoscope. It is contemplated by the invention that in general, any guidewire restraint mechanism preferably provides distal ports for enabling endoscope optics and the operation of endoscope channels in addition to the working channel. While not explicitly shown, all of the guidewire restraint mechanisms described below can be provided with such.

The guidewire can be constructed in the conventional manner, preferably of a metal that is characterized by limited longitudinal flexibility and torsional rigidity such that control motions applied to the proximal end of the guidewire, at the proximal port of the endoscope, are transmitted to the distal tip of the guidewire, even when that distal tip is distally extended beyond the distal port of the endoscope at an internal body lumen location. The guidewire can be provided in the conventional manner as stainless steel, nitinol, or other material, and can be coated with plastic, e.g., polytetrafluoroethylene (PTFE), or other suitable coating. Variation in stiffness along the guidewire length can also be provided in the conventional manner. The guidewire material is preferably more maneuverable than the working catheter material. This enables the guidewire to act as a support for the catheter as the catheter is advanced or withdrawn over the guidewire. The working catheter can be formed of any conventional catheter material, e.g., nylon, PTFE, polyvinylchloride, or other suitable material.

In use, the endoscope 10 is first advanced through an internal body lumen to the vicinity of a procedure site, with the restraining cap 24 in place over the distal port 14 of the endoscope. Then the guidewire 18 is advanced through the endoscope and out the distal port 14 through the hole 26 in the restraining cap. Sufficient longitudinal force is to be exerted on the guidewire to overcome the restoring force of the gripper lip 28 and thereby to push the guidewire through the opening 26. The guidewire distal tip 22 is then advanced to a location such as a position beyond an intended procedure site. The catheter 16 is then advanced along the guidewire through the endoscope working channel and sufficient longitudinal force is to be exerted on the

catheter to overcome the restoring force of the gripper lip 28 and thereby to push the catheter through the restraining cap opening 26.

In an alternative scenario, the catheter is partially advanced over the guidewire before the guidewire and catheter are together advanced through the endoscope working channel and through the restraining cap opening. In a further alternative scenario, the catheter is advanced through the endoscope working channel without prior advancement of a guidewire. A guidewire is then later advanced through the catheter if/when necessary to navigate a difficult region of an internal lumen, or to prepare for a catheter exchange, as described below. Fig. 1A illustrates a configuration achieved for any of the these scenarios, after a guidewire and a catheter have been advanced to the vicinity of a procedure site.

Referring to Fig. 1B, after use of the catheter at the procedure site is completed, the catheter is partially withdrawn, such that its distal end is at a position proximate of the restraining cap 24 at the distal end of the endoscope 10. During this partial catheter withdrawal, the proximal end of the guidewire is preferably held steady to maintain its position at the procedure site. This can be achieved through, e.g., manual retention by an operator, or through a mechanized device that is provided at, e.g., the proximal port of the endoscope. To enable this proximal retention, the guidewire must be sufficiently long that the proximal end of the guidewire extends beyond the proximal end of the catheter as the catheter is partially withdrawn to this position.

Upon withdrawal of the catheter proximate of the restraining cap 24, the gripper lip 28 of the opening 26 in the restraining cap contacts the guidewire 18 and restrains it. At this point, the catheter 16 can then be fully withdrawn from the endoscope while the gripper lip 28 maintains the guidewire in-position by substantially restraining longitudinal proximal movement of the guidewire. Retention of the proximal end of the guidewire is then no longer required. The restraining cap and gripper lip materials are characterized by a restoring force that is greater than the frictional force

between the catheter and the guidewire as the catheter is withdrawn over the guidewire. This ensures that during catheter withdrawal proximate of the cap, the guidewire is maintained at its distal position without the need for proximal guidewire retention.

Restraint of the guidewire by the gripper lip is further maintained as a second catheter is advanced along the guidewire to the procedure site. In the manner described above, longitudinal force is to be applied to the advancing catheter to push the catheter through the gripper lip opening. Once the proximal end of the catheter has been distally advanced beyond the proximal end of the guidewire, proximally external to the endoscope, and the distal end of the catheter has been pushed through the gripper lip, the proximal end of the guidewire is then preferably held steady manually as the second catheter is distally advanced to the procedure site. As explained above, in accordance with the invention this condition is enabled by employing a guidewire that is sufficiently long that its proximal end extends beyond the proximal end of the catheter when the catheter distal end has been advanced through the gripper lip.

Referring to Fig. 1D, illustrating an example adaptation of the gripper lip and restraining cap of Figs. 1A-C, the restraining cap 24 can be provided with an annular indentation, or thinned region 27, that is located radially within the working channel radius. This indentation 27 provides a distal hinge location in the restraining cap. When the guidewire 18 is gripped by the gripper lip 28, a condition shown in the figure with solid lines, the lip remains substantially orthogonal to the longitudinal axis of the guidewire, given the radius of the guidewire and the size of the hole in the gripper lip. But when both the catheter 16 and the guidewire are distally extended through the gripper lip 28, a condition shown in the figure with dotted lines, the gripper lip is pivoted hinged distally by the catheter. This pivoting of the gripper lip at its hinge point ensures that it is flexible enough to allow passage of the catheter, given that the hole in the gripper is relatively small. The gripper lip hole and

hinging indentations are preferably designed based on the guidewire and catheter radii and materials characteristics.

The restraining cap is an example of a passive, automatic, self-activating guidewire restraint provided by the invention. The gripper lip of the restraining cap automatically engages the guidewire when the working catheter is withdrawn proximate of the gripper lip, with substantially no engagement delay. For many applications this self-activating characteristic is preferable in a general effort to reduce the complexity of the rapid catheter exchange procedure.

It can be preferable for some applications, however, to have access to a guidewire restraint actuation mechanism that enables an operator to control the timing of guidewire restraint during a rapid catheter exchange procedure. Referring to Fig. 2A, there is shown in partial cross-section a restraint configuration provided the by invention that includes such a mechanism. Here the restraining cap 24 disposed at the distal end of the endoscope 10 includes a gripper lip 28 at an opening 26 in the restraining cap 24, but unlike the configuration of Figs. 1A-B, this gripper lip is not automatically in-position to engage the guidewire. The restraining cap and gripper lip can be provided as the materials described for the configuration of Figs. 1A-B above.

As shown in the figure, the gripper lip 28 is provided with a circumferential passage 32 through which is threaded a pull cord 34. The pull cord traverses the circumference of the passage 32 in the gripper lip 28 and extends out of the passage and down the working channel 12 of the endoscope. Preferably the pull cord extends through the entire length of the endoscope and is accessible at the proximal port of the endoscope. The pull cord can be actuated directly or if desired, can be configured in a handle grip or other suitable arrangement like that conventionally employed for other endoscopic control functions. Preferably, such a handle grip should provide a robust mechanism that reliably grips and holds the pull cord when actuated and that reliably completely releases the pull cord upon deactivation.

The pull cord is formed of a suitable material, such as, e.g., plastic, nylon, PTFE, stainless steel, suture thread, or other material, provided in a suitable configuration, e.g., as a cable or a braid of, e.g., fiber, fine wire, or other suitable material. The pull cord preferably does not stretch. The length of the pull cord is preferably sufficient to provide a reasonable length that extends beyond the proximal end of the endoscope.

Fig. 2A illustrates a condition in which the pull cord has not been activated. In this condition, the opening 26 in the restraining cap is of a diameter sufficient to allow passage of a guidewire and catheter through the opening without engagement by the gripper lip. Preferably, the opening 26 is about the diameter of the endoscope channel to enable ease of passage of the working catheter through the opening. The guidewire 18 and catheter 16 can thus be distally advanced through the endoscope and through the restraining cap to an intended procedure site with a minimum of longitudinal force application.

Once a procedure step is completed using the catheter, the catheter is then partially withdrawn, as shown in Fig. 2B, such that its distal end 20 is proximal of the gripper lip 28 of the restraining cap 24. This condition can be confirmed visually using the optics that are conventionally provided in the endoscope. The proximal end of the guidewire is preferably maintained steady during this partial withdrawal. At this point, as shown in Fig. 2C, actuation of the pull cord 34 in the direction shown by the arrow, at the proximal end of the endoscope working channel, can be initiated to cinch the gripper lip 28 for engagement with the guidewire 18 to eliminate the need for proximal guidewire retention. Once the gripper lip is tightened to engage the guidewire, the gripper lip snaring of the guidewire substantially restrains longitudinal movement of the guidewire, whereby the catheter can be entirely withdrawn over the guidewire out the endoscope working channel while the guidewire is maintained in place distally.

After removal of a first catheter for advancement of a second catheter in its place, it can be preferable for many applications to retain the pull cord in

its activated position such that the gripper lip engagement of the guidewire is maintained. This provides longitudinal stability of the guidewire as a second catheter is advanced over the guidewire through the endoscope. Once the second catheter distal end is advanced to approach the restraining cap at the endoscope distal port, release of the pull cord reopens the gripper lip opening in the restraining cap to enable passage of the second catheter through the distal port. This gripper lip reopening is due to the elasticity of the restraining cap. The restraining cap thereby provides an automatic restoring force mechanism that opposes the manual activation of the restraint. As the second catheter is then distally advanced beyond the endoscope to the procedure site, the guidewire is preferably held in place at its proximal end.

It is to be recognized that the invention contemplates a reversal of the activated cinching-automatic release configuration. Specifically, the gripper lip passage can be configured to automatically engage the guidewire, in the manner of the configuration of Figs. 1A-B, with pull cord activation initiated to release the gripper lip engagement. The size of the opening in the restraint cap and the gripper lip material and geometry are here selected to automatically engage a guidewire.

In a further adaptation, illustrated in proximal end view in Figs. 2D-E, the gripper lip 28 is composed of discontinuously segmented pull cord passages rather than a continuous passage as in Figs. 2A-C. In this segmented configuration, when the pull cord 34 is not proximally actuated, as in Fig. 2D, the gripper lip provides access in the working channel 12 for both a guidewire and a catheter. When the pull cord 34 is proximally actuated, as in Fig. 2E, the segments of the gripper lip cooperate to encircle and grip the guidewire 18. The segmentation of the gripper lip can be preferable, for some gripper lip materials, to ensure that the lip does not bind on itself when the pull cord is actuated to tighten the lip on a guidewire.

For some applications and for some endoscope designs, it can be preferable to minimize the number of elements that are in the working channel 12. To that end, the invention provides a configuration, illustrated in

partial cross-section in Figs. 3A-C, wherein the pull cord 34 threaded through the gripper lip passage 32 extends outside of the endoscope rather than through the working channel of the endoscope. As in the configuration of Figs. 2A-C, the pull cord here extends the length of the endoscope and is available at the proximal end of the endoscope for actuation of the gripper lip engagement with the guidewire.

If desired, the pull cord can be restrained at one or more points along the external endoscope wall to ensure that the cord does not stray from the endoscope as the endoscope is advanced and withdrawn through an internal body lumen. Preferably, such pull cord restraint does not hinder longitudinal proximal actuation of the pull cord. The cord restraint can be provided as, e.g., a sleeve such as a shrink sleeve, a band, tape that adhesively attaches to itself but not other materials, or other suitable restraint configuration.

In operation of the endoscope-external pull cord activated guidewire restraint, as shown in Fig. 3B, once the distal end 20 of the catheter 16 is withdrawn proximate of the gripper lip 28, the pull cord can be activated, as shown in Fig. 3C, in the direction of the arrow, to cinch the gripper lip about the guidewire and maintain the guidewire in-position as the catheter is withdrawn along the guidewire and further, if desired, also as a different catheter is then advanced along the guidewire.

Referring to Fig. 4A, in accordance with the invention the gripper lip 28 of the restraining cap 24 on the distal end of the endoscope can be augmented with a hollow gripper tube 36 also attached to the restraining cap and encircling an opening in the cap coincident with the distal port of the endoscope working channel. The gripper tube can be formed of the material employed for the restraining cap or can be formed of a distinct material; suitable materials include a plastic mesh, an elastomer, rubber, TPE, or other suitable material. The inner diameter of the tube is preferably sufficient to allow passage of a catheter through the tube; it is therefore preferred that a relatively thin tube be employed. The tube length should be sufficient to provide adequate gripper surface against the guidewire, and as a result, is

generally material-dependent for most applications. The tube length can be, e.g., between about 2 mm and about 8 mm.

In the example configuration shown, the gripper tube and distal gripper lip extend distally beyond the distal restraining cap 24. In the manner described above, a pull cord 34 is provided through the passage 32 in the gripper lip and extending through the working channel of the endoscope to be accessed at the proximal end of the endoscope for manual actuation.

In the condition shown in Fig. 4A, wherein the pull cord is not activated, a catheter 16 and guidewire 18 can be distally advanced through the gripper lip 28 to an intended procedure site. After carrying out a procedure step with the catheter, the catheter is partially withdrawn, as shown in Fig. 4B, proximate of the restraining cap 24 while the proximal end of the guidewire is maintained. Then as shown in Fig. 4C, actuation of the pull cord 34 is initiated to cinch down the gripper lip 28 and compress the gripper tube 36 both to engage the guidewire for substantially restraining longitudinal motion of the guidewire as the catheter is withdrawn. Proximal retention of the guidewire can at this point be released. As explained previously, this engagement with the guidewire can be maintained after the catheter is removed while a second catheter is advanced over the guidewire.

In an alternative configuration, referring to Fig. 5A, the gripper tube 36 can be configured to extend proximally from the distally-located restraining cap 24 into the working channel 12 of the endoscope 10. The restraining cap is distally external to the distal port of the endoscope, but the gripper tube is internal to the working channel and forms a co-linear passage within the working channel. Here a pull cord 34 is attached to the proximal end of the tube 36 at at least one attachment point 38, which can be formed as, e.g., a hole in the tube. No gripper ring is provided at ends of the gripper tube, which is connected directly to the restraining cap.

When the pull cord 34 is not activated, the gripper tube remains in an un-actuated position in the working channel, in an unobstructed configuration that allows a guidewire and catheter to be distally advanced through the

gripper tube and out the distal port of the working channel. After completion of a procedure step with the catheter, the catheter is partially withdrawn, proximate of the gripper tube 36, without engagement with the tube, as shown in Fig. 5B, while the guidewire is held steady at its proximal end. Then, upon proximal activation of the pull cord 34 as indicated by the arrow in Fig. 5C, the walls of the gripper tube are stretched proximally to engage the guidewire 18 around its circumference, given that the tube encircles the guidewire. This engagement substantially maintains the in-position location of the guidewire at the procedure site without the need for retention of the guidewire at its proximal end.

Proximal activation of the pull cord 34 is retained as the catheter is withdrawn to hold the guidewire in-position. The guidewire can further be held in-position as a second catheter is advanced over the guidewire by maintaining the proximal activation of the pull cord. Upon release of the pull cord, the elasticity of the gripper tube causes the tube to regain its unobstructive configuration, shown in Fig. 5A. Then, while the proximal end of the guidewire is held steady, the catheter can be distally advanced to the procedure site.

Further adaptations of the gripper tube 36 are contemplated by the invention. For example, the gripper tube can partially extend beyond the distal port of the endoscope working channel, e.g., by about 0.25 inches. A gripper lip can be provided at the distal port location of the restraining cap 24, at the proximal end of the gripper tube, or at both ends.

In one adaptation, illustrated in partial cross-section in Fig. 6A, the gripper tube 36 is disposed distally external to the distal port 14 of the endoscope in a restraining piston housing 37 and around which is provided a piston spring 39. The tube 36 and housing 37 are each provided with an opening that aligns with the endoscope distal port 14. In one example configuration, shown in Fig. 6B for the condition in which the distal end 20 of a catheter 16 is proximate of the gripper tube 36 and a guidewire 18 extends through the gripper tube, the tube opening 41 can be tapered from a first

proximal diameter that accommodates a catheter to a smaller distal diameter that is as small or smaller than the guidewire diameter.

The gripper tube can be formed of a solid or mesh, flexible material like the materials described above in connection with Figs. 4A-C for producing a gripper tube, here with a spring provided around the material. Alternatively, the tube can be eliminated and a spring alone provided. The spring, which can be provided as a conventional metal spring or other suitable configuration, is preferably designed with a restoring force and corresponding number of spring turns after empirical testing to determine the required spring restraining force on the guidewire. The piston housing can be formed of a suitable material that can be the same material as the gripper tube.

In an un-actuated condition, shown in Fig. 6A, a catheter 16 and a guidewire 18 can be distally advanced through the endoscope working channel 12 and out the distal port 14 through the gripper tube 36 to an intended procedure site. The gripper tube material is of sufficient flexibility that the catheter and guidewire can be pushed through the central opening in the tube. Once a procedure step is completed with the catheter, the catheter is partially withdrawn, proximate of the distal port 14 of the endoscope, through the gripper tube, as shown in Fig. 6B, while the guidewire is held steady at its proximal end.

Referring to Fig. 6C, in an activated condition, the distal wall 43 of the piston housing 37 moves proximally against the gripper tube, compressing the spring 39 and buckling or compressing the gripper tube 36. This in turn causes the walls of the central gripper tube opening to engage with the guidewire and substantially restrain guidewire longitudinal movement by frictional force. The catheter can then be fully proximally withdrawn over the guidewire while the guidewire is maintained in-position at the procedure site without the need for retention at its proximal end.

The invention contemplates a range of piston actuation mechanisms. In a first example scenario, the piston is self-actuating, in that it is normally in a state of buckling or compression. As with the restraining cap of Figs. 1A-B,

this arrangement relies on the application of longitudinal force to a catheter and guidewire to push the catheter and guidewire distally through the gripper tube to an intended site. When the catheter is withdrawn from the gripper tube, the frictional force applied to the guidewire by the tube is greater than the frictional force applied to the guidewire by the withdrawing catheter.

In a further example actuation mechanism, illustrated in partial cross-section in Fig. 7A, one or more pull cords 34, 35 are provided attached to, e.g., the distal end of the gripper tube 36, the spring 39, or the distal piston wall 43. The pull cords extend through the endoscope working channel 12 to the proximal end of the endoscope for actuation. As in the scenario of Fig. 6A, in an un-actuated condition, in Fig. 7A, a catheter and a guidewire can be distally advanced through the gripper tube 36 at the endoscope distal port. At the completion of a procedure with the catheter, the proximal end of the guidewire is maintained steady as the distal end of the catheter is withdrawn proximal of the gripper tube. Then, as shown in Fig. 7b, when the distal end 20 of the catheter 16 is proximate of the gripper tube, the one or more pull cords 34, 35 can be proximally activated, in the direction of the arrow in Fig. 7C, to compress the spring 39, collapse the distal piston wall 43, and buckle or compress the gripper tube 36. The guidewire is thereupon engaged within the central opening of the gripper tube and longitudinally restrained.

Upon withdrawal of a first the catheter, a second catheter can be advanced over the guidewire with the guidewire position maintained by the pull cord actuation of the gripper tube. Release of the gripper tube returns the piston configuration to the condition of Fig. 7A, whereupon the second catheter can be distally advanced through the gripper tube to a procedure site as the guidewire is held steady at its proximal end.

The invention contemplates a range of piston actuation mechanisms. For example, the pull cords 34, 35 shown in Figs. 7A-C can be provided exterior, rather than interior, to the endoscope. Pneumatic actuation can be employed, in which case the gripper tube can operate as a bladder, with the

outer portion resisting pressure from the bladder whereby the inner tube collapses on the guidewire to restrain the guidewire.

Referring to Fig. 8A, the invention provides a further guidewire restraint configuration in which a guidewire restraining wedge 40 is provided external to the distal port 14 of the endoscope working channel 12. The restraining wedge 40 is connected to a pull cord 34 which extends through the working channel 12 and is accessible at the proximal port of the working channel. In the condition illustrated in Fig. 8A, the wedge 40 is aside of the working channel distal port 14, allowing a catheter 16 and a guidewire 18 to be distally advanced through the distal port in an unobstructed manner toward an intended procedure site. This restraint configuration can be preferable for many applications because vision and irrigation ports of the endoscope are not occluded by a restraining mechanism.

Once use of the catheter is complete, the catheter is then partially withdrawn, proximate of the distal port 14 of the working channel 12, as shown in Fig. 8B, as the guidewire position is maintained at the proximal guidewire end. Proximal activation of the pull cord 34 in the direction indicated by the arrow in Fig. 8C then pulls the wedge 40 into the distal port 14 to engage the guidewire 18 against an internal wall of the working channel at the distal port and to thereby restrain longitudinal movement of the guidewire. The catheter can then be completely withdrawn over the guidewire without the need for proximal retention of the guidewire. When a first catheter is completely withdrawn from the endoscope, proximal activation of the pull cord can be maintained to hold the guidewire in-position as a second catheter is advanced distally along the guidewire through the endoscope. Upon approach of the second catheter to the distal port 14 of the endoscope working channel, release of the pull cord enables pushing aside of the wedge 40 by the second catheter as it passes through the distal port. The guidewire is then to be held at its proximal end while the second catheter is distally advanced to the procedure site.

Given the restraining action of the wedge against the guidewire, the wedge geometry preferably is selected to provide an effective wedging surface and to prohibit permanent lodging of the wedge in or at the port of the working channel. At least one dimension, or feature, of the wedge is therefore preferably greater than the working channel diameter. The wedge can take the geometry of a sphere in the manner shown, either solid or hollow, or as a half-sphere or donut, or alternatively as a cone or as an elliptical, triangular, partially- or fully-conical, or other suitable geometry. The wedge can be formed of plastic, rubber such as an elastomer, metal, or other suitable material.

In an alternative configuration, illustrated in partial cross-section in Fig. 9A, the guidewire wedge 40 is attached to an external wall of the endoscope by a restraining band 42 extending distally external to the distal port. The band can be attached, e.g., as shown, along the external longitudinal wall of the endoscope, with at least a portion of the band encircling the endoscope. Preferably the restraining band includes a free arm 45 that is directly connected to the wedge 40. The restraining band and can be formed of, e.g., an elastomer, or preferably silicone. The restraining band 42 can be frictionally attached to the endoscope by stretching the band over the endoscope distal port in the manner described above with regard to Figs. 1A-D.

The free arm 45 of the restraining band is preferably of a length selected such that in a condition like that shown in Fig. 9A in which the pull cord 34 is not activated, the elasticity of the band maintains the wedge 40 aside from the distal port 14 of the endoscope working channel 12. This allows a catheter and guidewire to be distally advanced through the distal port. When the catheter is then withdrawn proximate of the distal port, as shown in Fig. 9B, proximal activation of the pull cord 34 in the direction of the arrow in Fig. 9C pulls the wedge 40 into engagement of the guidewire against the distal port wall to maintain the guidewire in-position. As with the mechanisms described above, the guidewire is to be maintained in-position at its proximal end while the catheter is withdrawn proximate of the distal port.

Once a second catheter is advanced to the distal port 14, release of the pull cord then allows the restraining band arm 45 to pull the wedge 40 aside from the distal port for distal advance of the second catheter through the port. The elastic restraining band and arm thereby provide an automatic restoring force mechanism that opposes the manual pull cord activation of the wedge restraint. In one preferable example scenario, the restraining band arm and the pull cord can be maintained in light tension against each other so that it can assured that the wedge is being pulled securely in position against the guidewire.

In a further alternative configuration, illustrated in partial cross-section in Fig. 10A, two wedges 44, 46 are provided connected to the restraining band 42. In one example, a first wedge 44 is connected directly to the band 42 and a second wedge 44 is connected to a free restraining arm 45 extending from the band 42. In this configuration, the pull cord 34 is connected to one of the wedges 46 and is provided with a cord extension 48 connected between the pull cord 34 and the other wedge 44.

In the manner described above, the elasticity of the restraining band and arm maintains the wedges aside from the distal port 14 of the endoscope working channel 12 when the pull cord is not proximally activated. This allows for the distal advance of a catheter 16 and a guidewire 18 through the distal port of the endoscope, as shown in Fig. 10A; and allows for proximal withdrawal of the catheter over the guidewire as shown in Fig. 10B.

Referring to Fig. 10C, once the catheter distal end is withdrawn proximate to the distal port 14, preferably as the proximal end of the guidewire baing held steady, proximal activation of the pull cord 34 activates the cord extension 48 and the two cords pull the two wedges 44, 46 into contact with the guidewire 18 at the distal port of the endoscope. The guidewire is in this condition held between the wedges at the distal port of the endoscope, whereby longitudinal motion of the guidewire is substantially restrained. Proximal withdrawal of a first catheter and distal advancement of a second catheter can at this point be carried out without the need for manual

maintenance of the in-position location of the guidewire. Then in the manner described above, upon release of the pull cord the restraining band 42 and arm 45 pull the two wedges aside from the distal port to produce the condition of Fig. 10A in which a catheter can be advanced through the endoscope distal port to the procedure site as the guidewire proximal end is retained.

The invention contemplates the use of a number of wedges greater than two. For example, three or more wedges and associated pull cords could be arranged around the working channel circumference. The shapes and materials of the wedges in the plurality can be varied to provide an optimum guidewire restraining action for a particular endoscope arrangement.

Turning to further guidewire restraint configurations provided by the invention, and referring to Fig. 11A, there are shown guidewire restraining cams 50, 52 that are each connected externally distal to the working channel 12 of the endoscope 10. Each cam 50, 52 is connected by a bias spring 56, 58, respectively, to an external bias frame 54. The bias frame 54 is in turn attached to the external wall of the endoscope.

The cams can be formed out of any suitable material, e.g., a plastic, nylon, elastomer, metal, or other material. Each cam is preferably of dimensions suitable for frictionally gripping a guidewire between the cams when they are in a closed configuration. The bias frame can be formed of a rigid material, e.g., plastic or metal, with an elastomer layer provided attached to the frame for frictionally connecting the frame to the endoscope by stretching the elastomer over the endoscope. The springs connecting the cams to the bias frame can be formed of metal, elastomer, or other suitable spring material. In an alternative scenario, each cam and its corresponding spring can be formed as a unitary body, for example, as a molded piece of, e.g., nylon, consisting of a bendable beam extending from a cam geometry to operate as a spring element. In either scenario, the restoring force of the spring is preferably designed based on measured or expected frictional forces required for restraining a guidewire between the cams.

A pull cord 34 is attached to one of the cams 50 and extends through the endoscope working channel beyond the proximal port of the working channel. A cord extension 48 is connected between the pull cord 34 and the other of the cams 52. The pull cord and extension cord can be provided as metal, plastic, or other suitable material and can be attached to the cams by crimping, snap fit, interference fit, keyhole connection, insert molding, ball or knot provided on an end and threaded through a hole in a cam smaller than the knot or ball, or other suitable connection.

In an un-actuated condition, shown in Fig. 11A, the bias springs 56, 58 pull the cams 50, 52 radially outward, away from the distal port 14 of the working channel. In this condition, a catheter 16 and guidewire 18 can be distally advanced through the distal port of the working channel to an intended procedure site. After use of the catheter at the procedure site, the catheter is then partially proximally withdrawn, through the distal port 14, as the guidewire position is maintained by retention at its proximal end.

Once the distal end 20 of the catheter is proximate of the cams 50, 52, as shown in Fig. 11B, proximal activation of the pull cord 34 in the direction indicated by the arrow in the figure pulls the cord extension 48 and in turn the cams 50, 52 closed. The two cams engage the guidewire 18 to substantially restrain longitudinal motion of the guidewire as the catheter is completely withdrawn from the endoscope. After a first catheter is withdrawn, a second catheter can be distally advanced over the guidewire as it is held secure by the cams. Upon approach of the second catheter to the distal port 14 of the endoscope, release of the pull cord 34 allows the bias springs to retract the cams and enable distal passage of the catheter between the cams. Then as the proximal end of the guidewire is held steady, the catheter can then be distally advanced to the procedure site. The spring bias of the cams therefore provides an automatic restoring force mechanism that opposes the pull cord activation to reset the cam arrangement.

The invention contemplates various adaptations of this cam restraint configuration. For example, the bias springs can be configured to bias the

cams in a closed rather than retracted configuration. In this scenario, a pull cord is not required; as in the gripper lip configuration of Figs. 1A-C, where the guidewire restraint is automatic. Longitudinal force must be applied to the catheter and guidewire to distally advance the catheter and guidewire through the closed cams. When the catheter is withdrawn, the contact force of the cams on the guidewire is stronger than the frictional force between the withdrawing catheter and the guidewire, whereby the guidewire is maintained in-position.

Referring to Fig. 11C, in a further adaptation not requiring a pull cord, a magnetic element 51, 53 is provided in each of the cams 50, 52, respectively. The magnetic element can be provided as neodimium, samarium, cobalt, or other suitable magnetic material, and is preferably selected based on the endoscopic tool material, to ensure magnetic attraction between the material. Attachment of the magnetic material to the cams can be accomplished by, e.g., gluing, insert molding, or other suitable process. The cam bias springs 56, 58 can be included to normally bias the cams apart in an unobstructed path distal to the endoscope working channel. In this scenario, when the catheter is proximally withdrawn proximate of the cams, magnetic force between the cams and the guidewire holds the guidewire in-position. The engagement force of the cams on the guidewire is sufficiently strong to withstand the frictional force between the catheter and the guidewire as the catheter is withdrawn over the guidewire. As can be recognized, the bias springs are not required; in the manner described above, a catheter can be longitudinally advanced and withdrawn through the magnetically-attracted cams.

Referring to Fig. 12A, in a further restraint configuration provided by the invention, there are provided restraining grippers 60, 62 each of which includes a proximal grip 64, 66, and a distal grip 68, 70, respectively. Each gripper 60, 62 is biased by a respective spring 56, 58, to a bias frame 65 that is attached externally to the endoscope 10 distally of the working channel distal port.

The distal grips 68, 70 are preferably formed of a high-friction material, e.g., an elastomer, silicon, TPE, urethane, or other material with a "sticky" surface for gripping onto a guidewire. In contrast, the proximal grips 64, 66 are preferably formed of a "slippery" material like PTFE, polyethylene (PE), nylon, DELRIN®, or other relatively hard material that does not impose a high coefficient of friction. Both pairs of grips preferably provide elongated gripping surfaces. As with the restraint configuration of Figs. 11A-11B, the springs 56, 58 connected to the grips can be distinct elements or can be of a unitary construction with the grippers 60, 62. If provided as distinct elements, the springs can be formed of a metal, e.g., stainless steel, or of an elastomer. The bias frame 65 can be provided as a rigid structure, e.g., plastic or metal, that is attached to the endoscope by, e.g., an elastomer cap in the manner described above for the configuration of Figs. 11A-B.

In one example bias configuration, the bias springs 56, 58 are arranged to provide a gripping force that tends to move the grippers toward each other, in a manner that obstructs a distal path that is coincident with the working channel of the endoscope. When a catheter 16 and a guidewire 18 are distally advanced through the endoscope working channel, a longitudinal force is to be applied to the catheter and guidewire to push apart the proximal grips 64, 66 for more distal advancement toward an intended procedure site. In the condition illustrated in Fig. 12A, the distal end 20 of the catheter 16 has just reached the proximal grips 64, 66 and is pushing the grips apart. The relatively larger-diameter catheter is gripped by the proximal grips 64, 66 with only minimal force, whereby there is enabled further distal advancement of the catheter, as well as the guidewire.

Referring to Fig. 12B, when a procedure step employing the catheter is completed, the guidewire is preferably retained at its proximal end as the catheter is partially withdrawn proximally through the endoscope channel. Once the catheter distal end is proximal of the proximal grips 64, 66, they tend toward a closed position, resulting in engagement of the distal grips 68, 70 with the guidewire 18. The relatively smaller-diameter guidewire is engaged

by the distal grips 68, 70 with a force that is larger than the force with which the proximal grips engaged the catheter. With the guidewire engaged by the distal grips 68, 70 a first catheter can be fully distally withdrawn over the guidewire from the endoscope without the need for proximal retention of the guidewire, and a second catheter can be advanced over the guidewire through the endoscope to the intended procedure site while the guidewire is maintained in-position by the gripper. Once the catheter is distally advanced beyond the proximal grips, it is preferable to retain the proximal end of the guidewire.

Like the configuration of Figs. 11A-B, in an adaptation of this configuration a magnetic element can be provided in either or both pairs of proximal grips 64, 66 and distal grips 68, 70. This scenario enables a magnetic guidewire restraint in the manner described above with regard to the configuration of Figs. 11A-B. In this adaptation, if the bias springs 56, 58 provide a normally-closed grip bias, the magnetic force between the grips and the guidewire enhance the guidewire engagement force of the grips. Alternatively, the bias springs 56, 58 can be configured to provide a normally-open grip bias, with the magnetic force acting to close the grippers onto and engage the guidewire. This scenario is particularly well-suited for use with a stainless steel guidewire. In a further magnetic grip adaptation, only the proximal grips 64, 66 are included, operating in the manner of the cams of Figs. 11A-B.

Turning to Fig. 13A, in a further guidewire restraint configuration provided by the invention, there is shown in partial cross-section a restraining plate 71 located externally to the endoscope working channel 12 and distal to the distal port of the working channel. The restraining plate 71 includes a passage 72 that is at least as wide, and preferably wider, than the working channel, and that is radially aligned with the working channel. The restraining plate is attached to the endoscope by a pivot 74 at one end of the plate and a spring 76 at the other end of the plate. A pull cord 34 is provided attached to the restraining plate 71 at a location relatively more close to the spring than the pivot. The pull cord extends through the passage 72 of the

plate 71 and through the endoscope working channel to the proximal port of the endoscope for proximal activation.

The restraining plate can be provided as a rigid material, e.g., a suitable metal or a suitable plastic, such as nylon or DELRIN®, or other suitable material. The pull cord can be attached to the restraining plate by way of, e.g., a mechanical joint like a crimp, a solder joint, an interference fit, a ball or knot provided on the end and through a smaller hole in the plate, insert molded, or other suitable attachment technique. The pivot is preferably formed of a plastic or elastomer material, e.g., polypropylene, that provides a robust, reliable connection that can flex repeatedly without fatigue. The spring is preferably provided as a metal, plastic, or other suitable material that is designed with a selected restoring force and number of turns based on a measured or expected force required to maintain the plate in a desired rotational position. The restraining plate 71 and bias spring 76 can be attached to the endoscope by a friction-fit elastomeric cap, in the manner of the configuration shown in Figs. 1A-D.

In one configuration, the spring 76 is biased to normally maintain the plate in a position rotated about the pivot, away from the endoscope, in the manner shown in Fig. 13B. To provide an unobstructed path from the distal port of the working channel through the restraining plate, the pull cord 34 is proximally actuated, in the direction of the arrow in Fig. 13A. In this condition, a catheter 16 and guidewire 18 can be distally advanced through the restraining plate to an intended procedure site. It is preferred that the pull cord be maintained in a proximally actuated condition during a procedure so that the catheter is not damaged and is unobstructed during the procedure.

After use of the catheter at the procedure site is complete, and with the pull cord retained in a proximally activated condition as in Fig. 13A, the proximal end of the guidewire is retained as the catheter is partially proximally withdrawn over the guidewire. When the distal end 20 of the catheter 16 is proximate of the restraining plate 70, release of the pull cord results, as shown in Fig. 13B, in pivoting of the restraining plate 70 to engage

the guidewire at a wall of the plate passage 72. The catheter can then be completely withdrawn from the endoscope with the guidewire maintained in-position by the restraining plate. A second catheter can then be distally advanced through the endoscope. Upon the distal end of the second catheter reaching the distal port of the working channel, the pull cord is again proximally activated to enable passage of the catheter through the plate, with the proximal end of the guidewire then held steady until the catheter is advanced to the intended site.

This configuration provides an automatic guidewire restraint actuation mechanism that opposes a restoring mechanism enabled by the pull cord activation. The configuration thereby is fail safe in the sense that the guidewire restraint is provided unless the pull cord is activated. This feature enhances the speed and safety with which a rapid catheter exchange can be carried out. The invention contemplates an adaptation of this configuration, however, in which the spring is provided to bias the plate in an un-pivoted condition like that of Fig. 13A. Here the pull cord 34 is attached to the plate 71 at a location relatively closer to the pivot 74 than to the spring 76. In this scenario, proximal activation of the pull cord pivots the plate to a guidewire engagement position like that of Fig. 13B. For this adaptation it can be preferable to maintain the pull cord external to the endoscope, rather than extending it through the working channel. Such an adaptation can also be applied to the configuration of Figs. 13A-B.

Referring to Fig. 14A, in a further guidewire restraint configuration provided by the invention, there is shown in partial cross-section a guidewire restraint bushing 80 in which is provided a passage 82 that is at least as large as the working channel 12 of the endoscope 10. In one example, the restraint bushing 80 is held in a socket in a restraining frame 84 by a spring element 86. Here the spring element is connected to the restraint bushing 80 and extends through the frame 84 to an outside wall of the frame. The frame 84 is connected to the endoscope with the restraint bushing positioned at a location that is distally external to the working channel of the endoscope. A pull cord

34 is connected to the restraint bushing 80 at a side opposite the ball connection to the spring element. The pull cord extends through the working channel for proximal activation at the proximal port of the channel.

The bushing can be produced of a metal, plastic, elastomer, or other suitable material, and can be configured in any convenient geometry. The spring element can be provided as a flexible elastic or metal spring with a designed restoring force, or alternatively, can be formed as one or more tabs connected between the bushing 80 and the frame 84 that allow single-axis rotation of the bushing. Such a tab or tabs can be provided as, e.g., molded elements. This configuration can be preferable for some applications in that is eliminates the need for a separate spring element 86 connected as shown in Fig. 14A.

In the configuration shown in Fig. 14A, the spring element 86 is biased to maintain the restraint bushing 80 in a position such that the passage 82 of the bushing is parallel with the distal port 14 of the working channel 12. In this configuration, a catheter 16 and a guidewire 18 can be distally advanced through the working channel and distal port of the endoscope to an intended procedure site.

When use of the catheter is complete, the guidewire is maintained steady at its proximal end and the catheter is partially proximally withdrawn over the guidewire. Once the distal end 20 of the catheter is proximate of the restraint bushing 80, as shown in Fig. 14B, proximal activation of the pull cord 34 in the direction of the arrow in the figure causes the bushing 80 to rotate and to engage the guidewire at a wall of the bushing passage 82. At this point proximal retention of the guidewire is no longer required while the catheter is completely withdrawn out of the endoscope. A second catheter can then be distally advanced through the endoscope to the distal port. When the distal end of the second catheter reaches the working channel distal port, the pull cord is released to allow the restraint bushing to rotate into a position in which the passage 82 of the bushing is parallel with the distal port of the working

channel. The guidewire is then maintained steady at its proximal end as the catheter is advanced to the procedure site.

As can be recognized, this restraint configuration can be adapted such that the spring element maintains the bushing in a rotated position like that of Fig. 14B. This configuration, like that of Figs. 13A-B, is fail safe in that the guidewire restraint is automatic, requiring manual de-actuation.

Referring to Figs. 15A-C, in a further guidewire restraint configuration provided by the invention, there is shown in partial cross-section a guidewire restraining wall 88 having a gripper tab 100 that can be rotated about a relatively thin hinge region 90 toward and away from the distal port 26 of the endoscope working channel 12. The restraining wall 88 distally extends from a restraint cap 96 that can be fit over the distal port of the endoscope. A pull cord 34 is connected to the restraining wall at, e.g., the gripper tab, and extends through the working channel for proximal activation at the proximal port of the channel. The cord can be connected to the restraining wall in any convenient fashion, e.g., using a knot 92 and washer 94 configuration as shown, or in another suitable configuration. Optionally, a contact wall 98 can be provided extending distally from the restraining cap opposite the restraining wall. The restraining and contact walls are preferably produced of an elastomeric material that enables the thin hinge region 90 to bend and that enables the thin hinge regions and adjacent regions to easily stretch.

In the configuration shown in Fig. 15A, the pull cord 34 has not been proximally activated. Here the gripper tab 100 is free to rotate away from the endoscope distal port 26. As a result, a catheter 16 and a guidewire 18 can be distally advanced through the working channel 12 and distal port of the endoscope, rotating the tab 100 aside to enable distal advance of both the guidewire and a catheter to an intended procedure site.

When use of the catheter is complete, the guidewire is maintained steady at its proximal end and the catheter is withdrawn such that its distal end 20 is proximate to the distal port, as shown in Fig. 15B. Then, as shown in Fig. 15C, proximal activation of the pull cord rotates the gripper tab 100

toward the distal port, engaging the guidewire between the contact wall 98 and the gripper tab 100. With the guidewire now held in-position by the restraining wall, retention of the guidewire position at its proximal end is not required as the catheter is completely proximally withdrawn from the endoscope. A second catheter can then be distally advanced through the endoscope to the distal port. When the distal end of the second catheter reaches the gripper tab 100, the pull cord is proximally released to allow the tab to rotate back to a position, as shown in Fig. 15A, in which passage of a catheter is accommodated. The guidewire is then maintained steady at its proximal end as the catheter is advanced to the procedure site.

In adaptations of this configuration, the contact wall 98 can be eliminated, whereby the gripper tab 100 cooperates with the edge of the endoscope distal port to contact the guidewire and maintain its position as a catheter is withdrawn and/or advanced.

Based on the discussion above it is apparent that the invention contemplates a very wide range of restraint configurations and adaptations. In general, the restraint configurations all include some restraining member that is positioned for enabling engagement of the member with an endoscopic tool, such as a guiding tool, for holding the tool in place as a catheter is proximally withdrawn or distally advanced over the tool. The inventors herein recognize that a wide range of guiding tools, beyond conventional guidewires, can be employed in conjunction with the restraint configurations of the invention. In all of the restraint configurations described, engagement of the tool by the restraining member is effected to take place at a location that is at least as distal as the endoscope distal port, i.e., engagement occurs at the distal port or distally external to the port; contact can additionally also occur proximally internal to the endoscope working channel.

The invention contemplates that for some applications it may be desirous to restrain an endoscopic tool, such as a guidewire, while an inner sheath, such as a working catheter, extends beyond the restraint of the invention, the catheter thereby interposing itself between the restraint and the

guidewire. For such applications, the restraint configurations of the invention can be employed with the catheter in place over the guidewire, so long as the mechanical impact of a selected restraint configuration on the catheter is acceptable. It is therefore to be recognized that direct contact of a tool such as a guidewire is not required; engagement of the tool by a restraint can be indirect, e.g., through an interposing catheter.

It is to be recognized that for various endoscope configurations and endoscopic tools, different of the restraint configurations of the invention can be found optimal. It is therefore preferred for those restraint configurations that require a connection to the endoscope that the connection be a releasable, non-permanent attachment. This enables the restraint configuration to be supplied as an endoscopic attachment that can be installed on the endoscope at the point of use and can be replaced or removed as necessary. Permanent attachment of a restraint configuration to an endoscope is also contemplated by the invention.

It is further to be recognized that the restraint configurations of the invention can be adapted for a wide range of endoscopes. For example, as explained earlier, side-viewing endoscopes and endoscopes including several working channels can be accommodated by the restraint configurations. Further, the restraint configurations place no limitations on accessories and tools employed at the proximal end of an endoscope.

The restraint configurations of the invention provide particularly elegant and adaptable mechanisms that enable, among other procedures, rapid catheter exchange procedures that previously required cumbersome and complicated techniques and equipment. Beyond rapid exchange procedures, the restraint configurations address the many requirements for securely and reliably maintaining an endoscopic tool in a selected position at a procedure site. It is recognized of course that those skilled in the art may make various modifications and additions to the restraint configurations described above without departing from the spirit and scope of the present contribution to the art. Accordingly, it is to be understood that the protection sought to be

afforded hereby should be deemed to extend to the subject matter of the claims and all equivalents thereof fairly within the scope of the invention.

We claim:

CLAIMS

1. An endoscopic tool restraint for restraining longitudinal movement of an endoscopic tool with respect to a distal port of an endoscope channel through which the tool can be distally advanced and proximally retracted longitudinally, the restraint comprising at least one restraining member disposed at least as distally as the endoscope channel distal port and positioned in spatial correspondence with the distal port to engage the tool when a distal end of the tool extends distally beyond the restraining member.

2. The endoscopic tool restraint of claim 1 further comprising a restraining connector connected between the restraining member and an exterior wall of the endoscope.

3. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a contact surface for making direct tool contact at least as distally as the endoscope channel distal port when a catheter is located in the endoscope channel over the tool with a distal end of the catheter proximate of the contact surface and a distal end of the tool extending distally beyond the contact surface.

4. The endoscopic tool restraint of claim 3 wherein the contact surface is oriented with respect to the distal port to exert against the tool, when in contact with the tool, sufficient contact force to restrain longitudinal movement of the tool when a catheter is longitudinally moved over the tool within the endoscope channel and a distal end of the catheter is proximate the restraining member.

5. The endoscopic tool restraint of claim 1 wherein the endoscopic tool comprises a guiding tool.

6. The endoscopic tool restraint of claim 5 wherein the guiding tool comprises a guidewire.

7. The endoscopic tool restraint of claim 1 further comprising a restoring member connected between the restraining member and the endoscope in a condition that opposes engagement of the tool by the restraining member.

8. The endoscopic tool restraint of claim 7 wherein the restoring member comprises a spring element.

9. The endoscopic tool restraint of claim 1 further comprising a restoring member connected between the restraining member and the endoscope in a condition that effects engagement of the tool by the restraining member.

10. The endoscopic tool restraint of claim 9 wherein the restoring member comprises a spring element.

11. The endoscopic tool restraint of claim 1 further comprising a restraining member activator connected to the restraining member and extending proximate a proximal port of the endoscope channel, the activator provided in a condition, when actuated at a proximal end, that effects engagement of the tool by the restraining member.

12. The endoscopic tool restraint of claim 1 further comprising a restraining member de-activator connected to the restraining member and extending proximate of a proximal port of the endoscope channel, the de-activator provided in a condition, when actuated at a proximal end, that opposes engagement of the tool by the restraining member.

13. The endoscopic tool restraint of claim 11 wherein the restraining member activator comprises a pull cord.

14. The endoscopic tool restraint of claim 13 wherein the pull cord is positioned within the endoscope channel.

15. The endoscopic tool restraint of claim 13 wherein the pull cord is positioned exterior to the endoscope channel.

16. The endoscopic tool restraint of claim 12 wherein the restraining member de-activator comprises a pull cord.

17. The endoscopic tool restraint of claim 16 wherein the pull cord is positioned within the endoscope channel.

18. The endoscopic tool restraint of claim 16 wherein the pull cord is positioned exterior to the endoscope channel.

19. The endoscopic tool restraint of claim 1 wherein the restraining member is disposed at the endoscope channel distal port.

20. The endoscopic tool restraint of claim 1 wherein the restraining member is disposed distally beyond the endoscope channel distal port, and further comprising a restraining member connector connected between the restraining member and an exterior wall of the endoscope.

21. The endoscopic tool restraint of claim 1 wherein the at least one restraining member comprises a plurality of restraining members each positioned in spatial correspondence with the distal port to engage the tool when a distal end of the tool extends distally beyond the restraining members.

22. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a gripper lip provided in a restraining cap over the endoscope channel distal port.

23. The endoscopic tool restraint of claim 22 wherein the gripper lip includes a circumferential lip passage in which is provided a pull cord extending proximally from the lip passage to a proximal end of the endoscope for activation of the gripper lip to engage the endoscopic tool when the cord is proximally actuated.

24. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a gripper tube provided in a restraining cap over the endoscope channel distal port, the gripper tube extending distally beyond the endoscope channel distal port.

25. The endoscopic tool restraint of claim 24 wherein the gripper tube includes a circumferential tube passage in which is provided a pull cord extending proximally from the tube passage to a proximal end of the endoscope for activation of the gripper tube to engage the endoscopic tool when the cord is proximally actuated.

26. The endoscopic tool restraint of claim 26 further comprising a restoring spring disposed in the gripper tube and provided in a condition that biases the gripper tube to effect engagement of the endoscopic tool.

27. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a gripper tube provided in a restraining cap over the endoscope channel distal port, the gripper tube extending from the endoscope channel distal port proximally, interior to the endoscope channel.

28. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a restraining wedge disposed distally to the endoscope channel distal port and connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope, the restraining wedge sized to engage the endoscopic tool when the pull cord is proximally actuated.

29. The endoscopic tool restraint of claim 28 further comprising an elastic restoring band connected between the wedge and an exterior wall of the endoscope.

30. The endoscopic tool restraint of claim 1 wherein the at least one restraining member comprises a plurality of restraining wedges each disposed distally to the endoscope channel distal port and connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope, the restraining wedges being sized to engage the endoscopic tool when the pull cord is proximally actuated.

31. The endoscopic tool restraint of claim 1 wherein the at least one restraining member comprises two restraining cams each disposed distally to the endoscope channel distal port and connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope, the restraining cams being sized to engage the endoscopic tool between the cams when the pull cord is proximally actuated.

32. The endoscopic tool restraint of claim 31 further comprising a bias spring connected to each cam for biasing the cams apart.

33. The endoscopic tool restraint of claim 1 wherein the at least one restraining member comprises two restraining cams each disposed distally to the endoscope channel distal port and each including a magnetic material

portion, the restraining cams being sized to engage the endoscopic tool between the cams.

34. The endoscopic tool restraint of claim 1 wherein the at least one restraining member comprises a pair of grippers, each gripper including a distal grip and a proximal grip, both distal and proximal grips disposed distally to the endoscope channel distal port, the grippers each connected to a spring element to bias the distal grips toward each other.

35. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a restraining plate hinged at one plate edge at the endoscope channel distal port and including a passage that can be aligned with the channel distal port when the plate is rotated against the port, the restraining plate connected by a spring to an exterior wall of the endoscope at a plate edge opposite the hinged plate edge, the spring biased to maintain the plate in a position in which the endoscopic tool is engaged by a wall of the plate passage, and the plate being connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope for opposing engagement of the tool when the cord is proximally actuated.

36. The endoscopic tool restraint of claim 1 wherein the restraining member comprises a restraining bushing disposed distally to the endoscope channel distal port and elastically connected to a bushing housing that accommodates rotation of the bushing, the bushing including a passage that can be aligned with the endoscope distal port by rotation of the bushing, and the bushing being connected to a pull cord extending proximally through the endoscope channel to a proximal end of the endoscope for rotating the bushing when the cord is proximally actuated.

37. The endoscopic tool restraint of claim 1 wherein the restraining member comprises an elastically deformable gripper sidewall connected to a

restraining cap over the endoscope channel distal port, the gripper sidewall including a pivot portion at which the sidewall can pivot proximally toward the endoscope channel distal port, a pull cord connected to the gripper sidewall and extending proximally through the endoscope channel to a proximal end of the endoscope for rotating the sidewall when the cord is proximally actuated .

38. The endoscopic tool restraint of claim 38 wherein the restraining cap includes a contact wall opposite the gripper sidewall and extending for a length sufficient to enable engagement of the endoscopic tool between the gripper sidewall and the contact wall when the gripper sidewall is rotated.

39. The endoscopic tool restraint of claim 1 wherein the endoscope channel distal port comprises a side-view distal port.

40. The endoscopic tool restraint of claim 1 wherein the endoscopic channel comprises a plurality of channels, the endoscopic tool distally advanced and proximally retracted through a selected one of the channels.

FIG. 1A

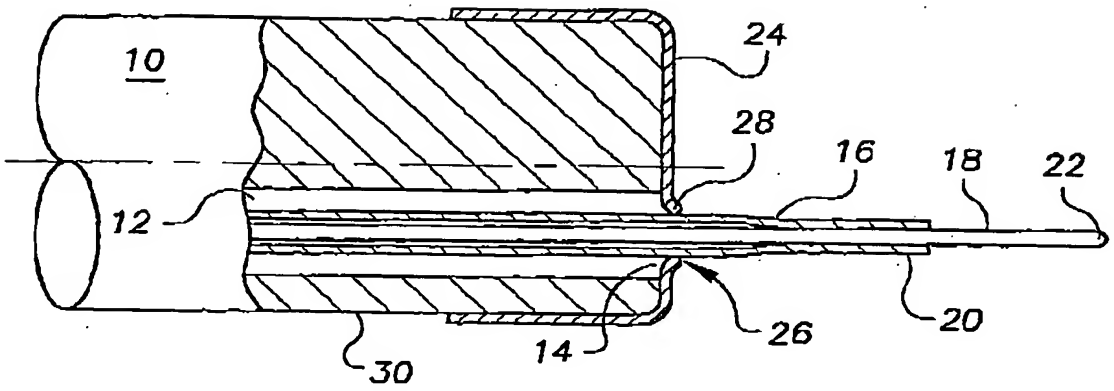

FIG. 1B

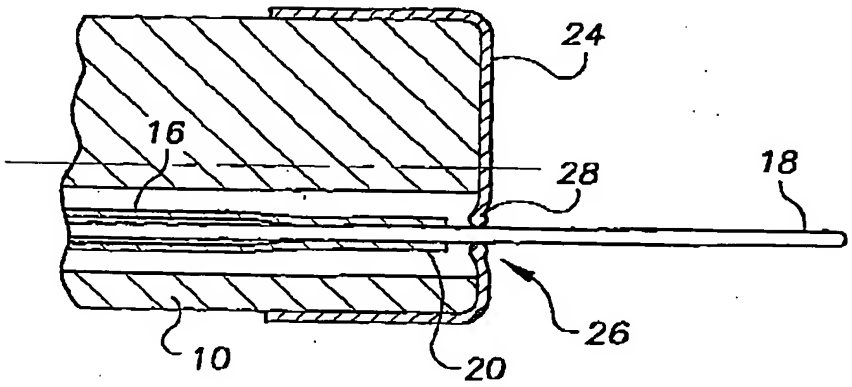

FIG. 1C

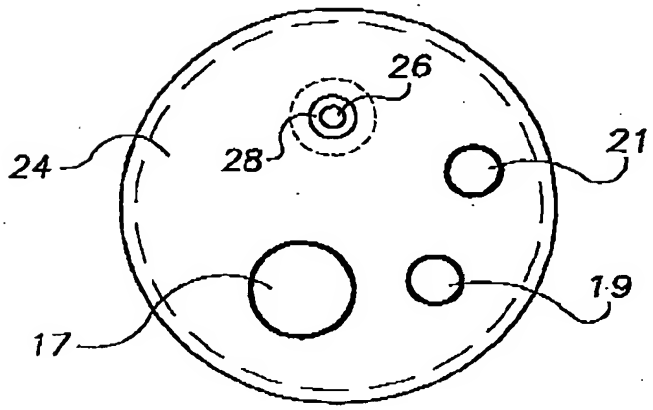

FIG. 1D

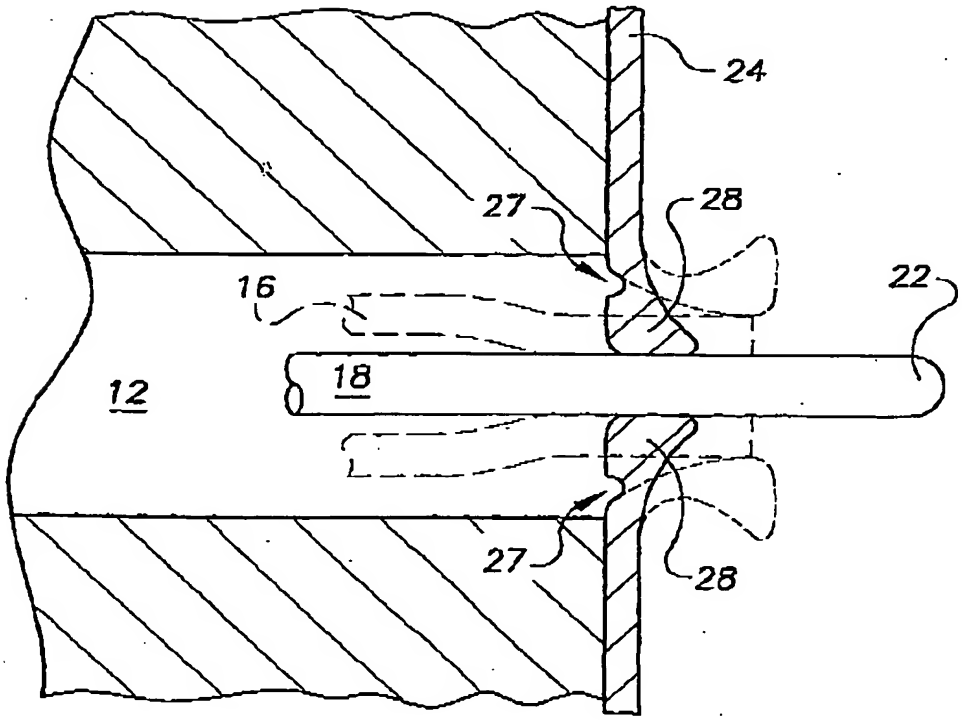

FIG.2A

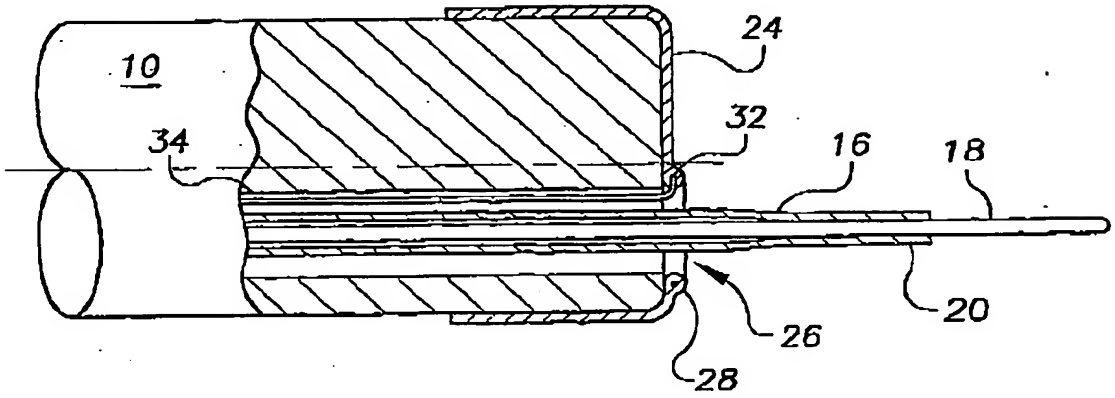

FIG.2B

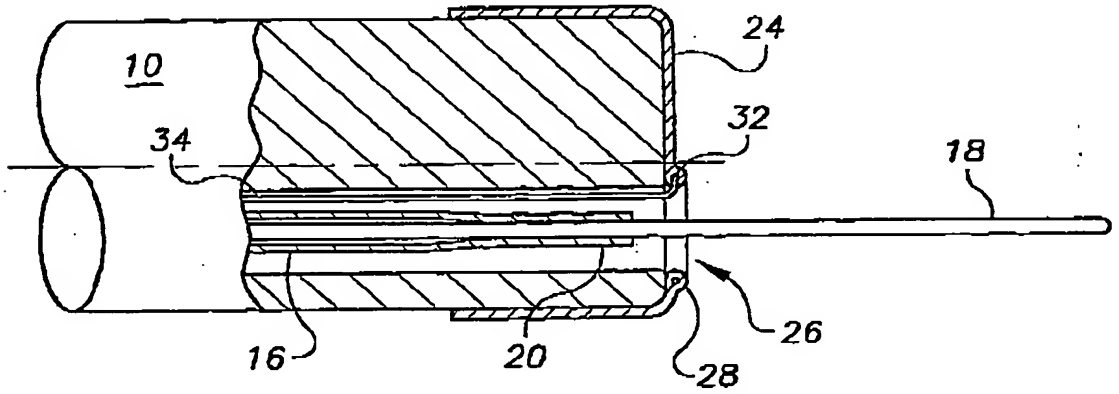

FIG.2C

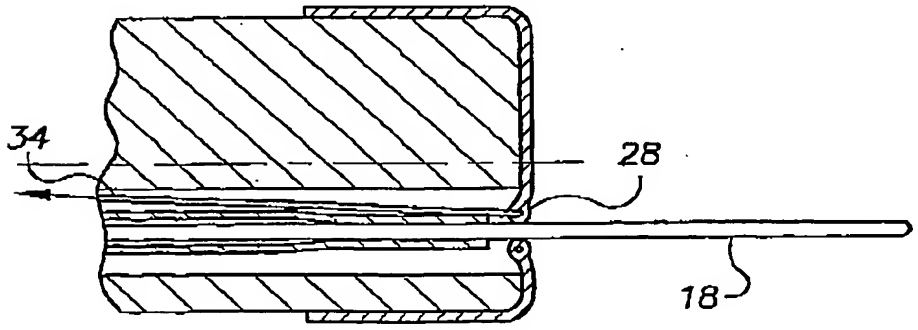

FIG. 2D

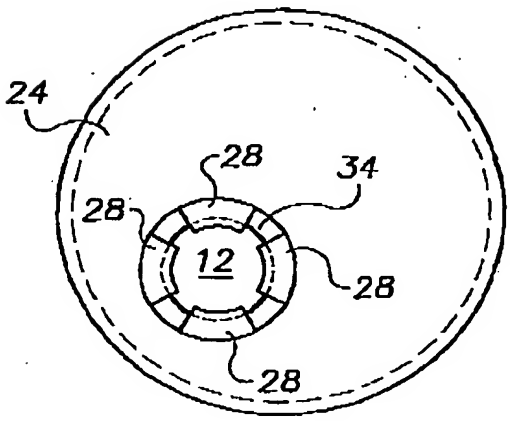

FIG. 2E

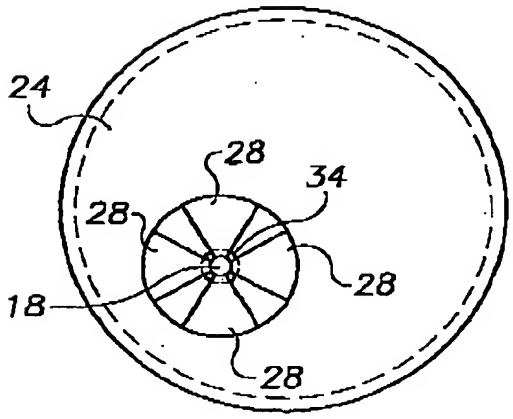

FIG. 3A

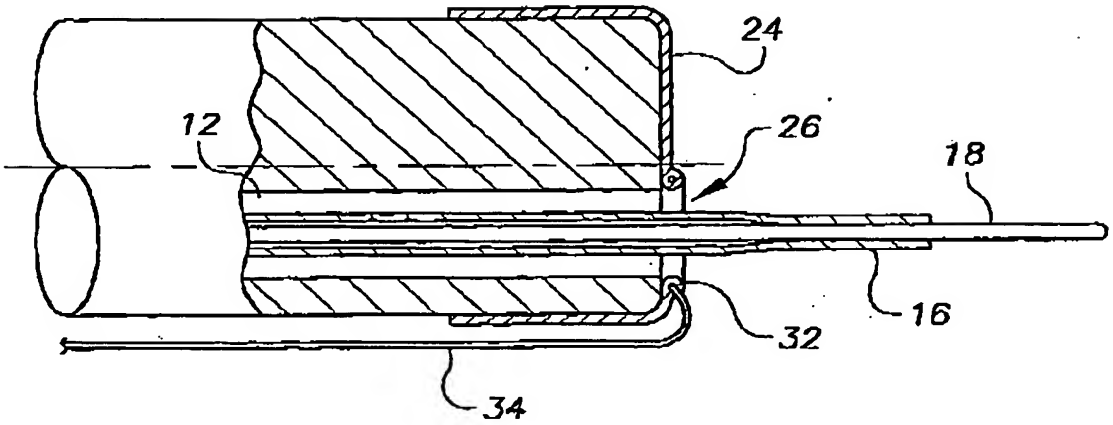

FIG. 3B

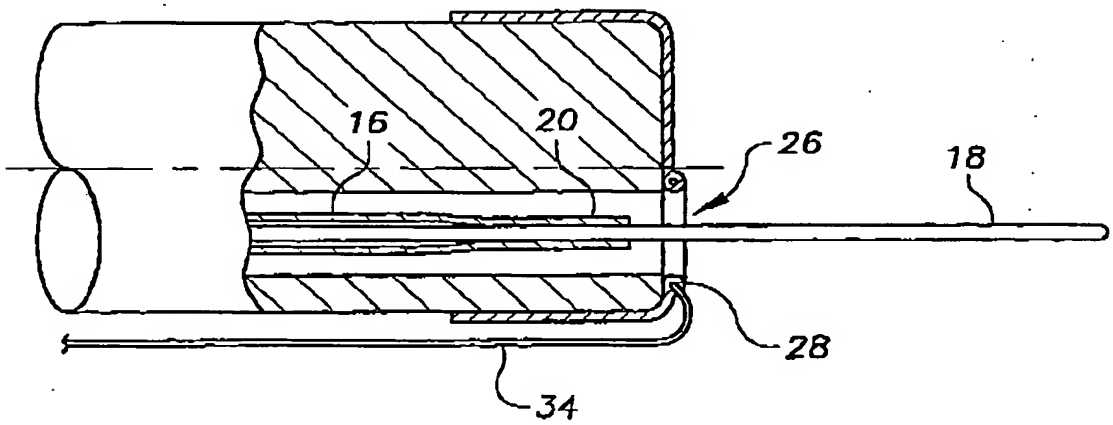

FIG. 3C

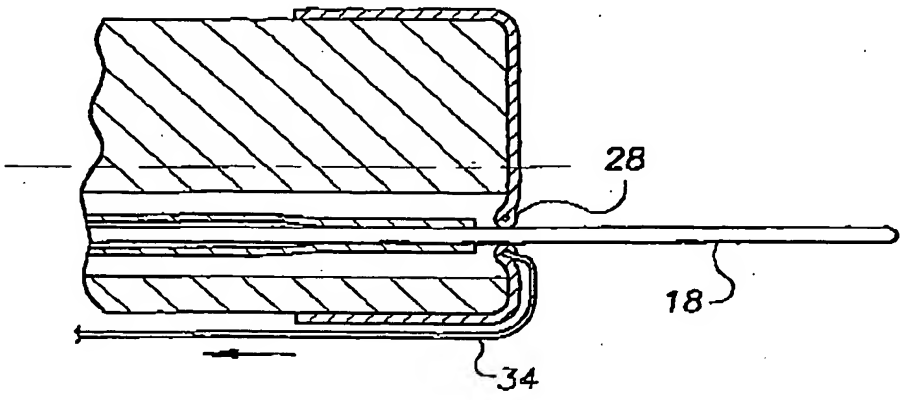

FIG. 4A

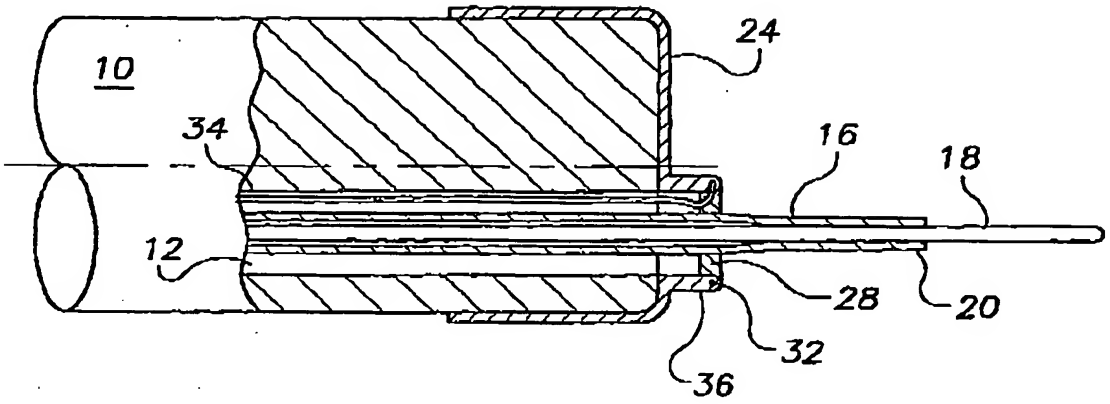

FIG. 4B

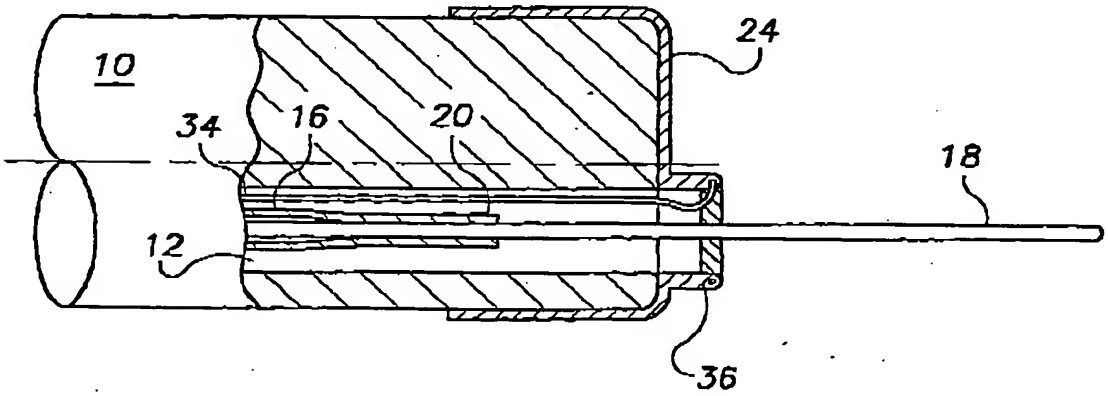

FIG. 4C

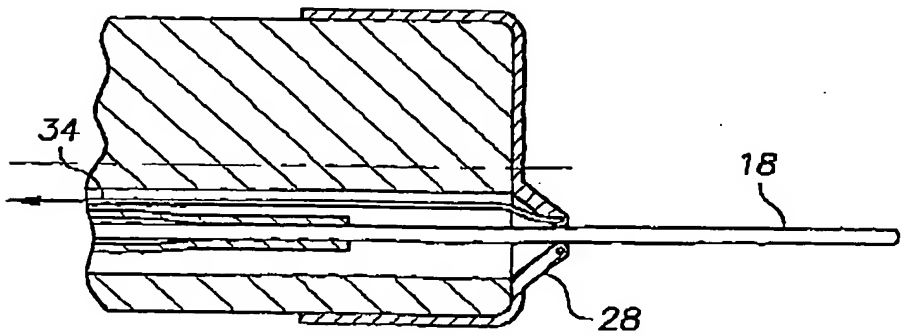

FIG.5A

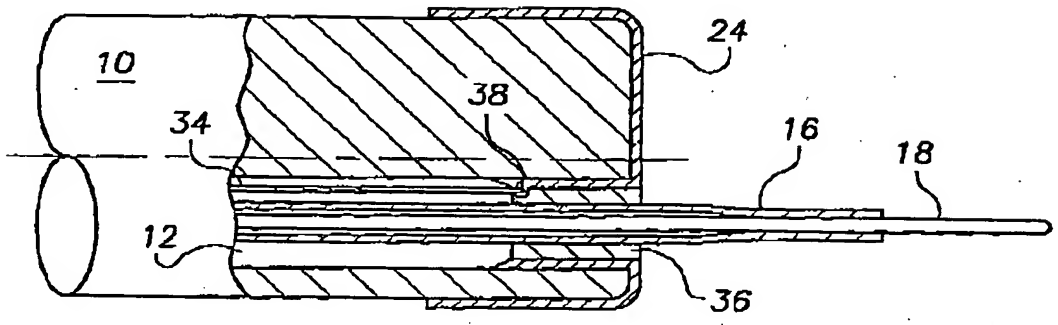

FIG.5B

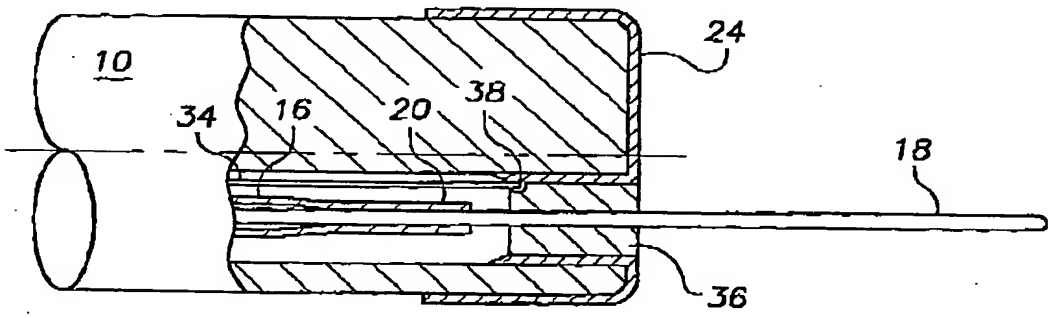

FIG.5C

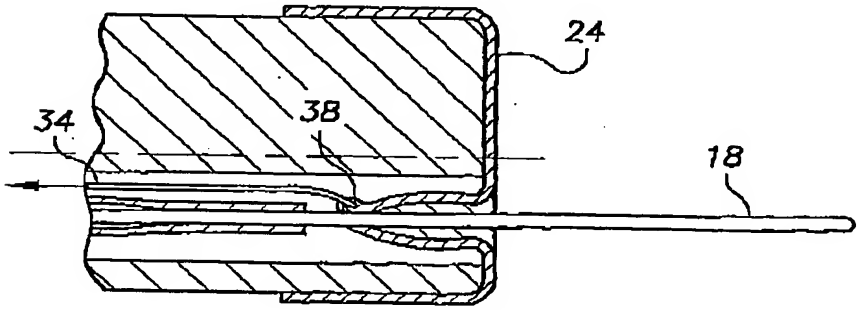

FIG. 6A

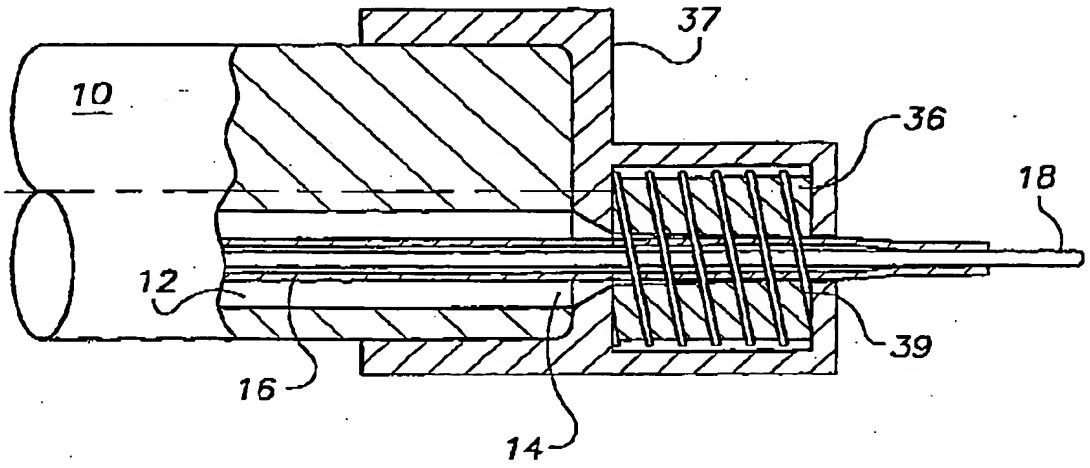

FIG. 6B

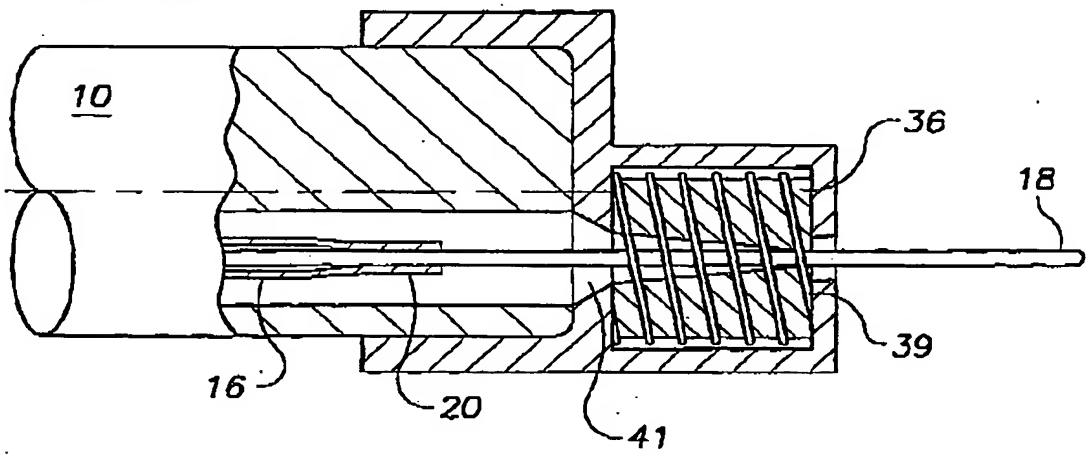

FIG. 6C

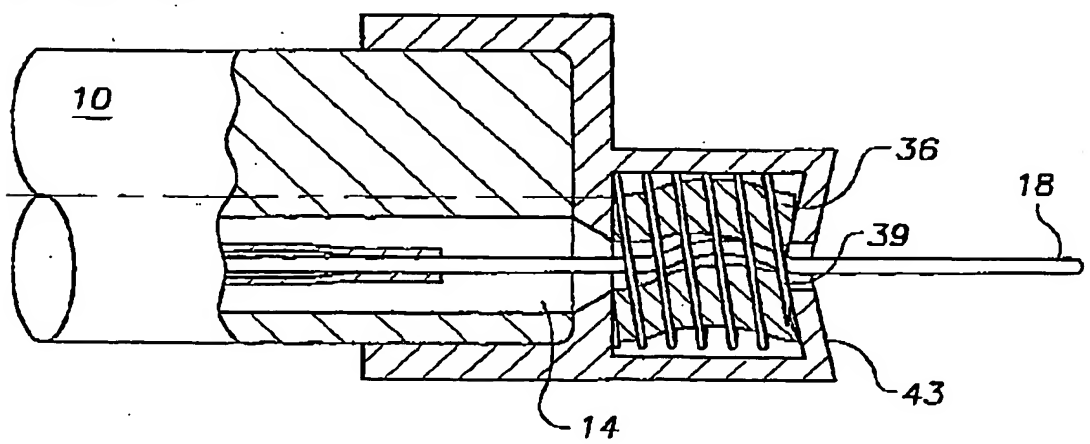

FIG. 7A

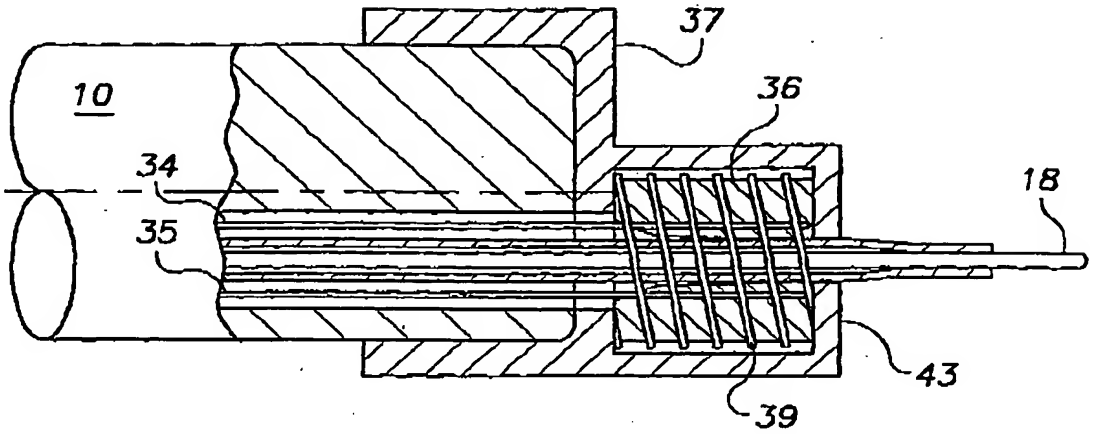

FIG. 7B

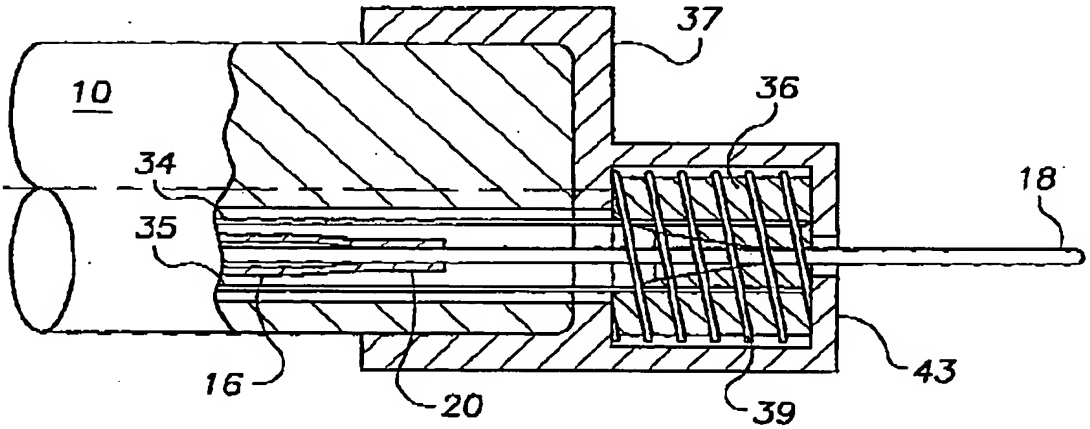

FIG. 7C

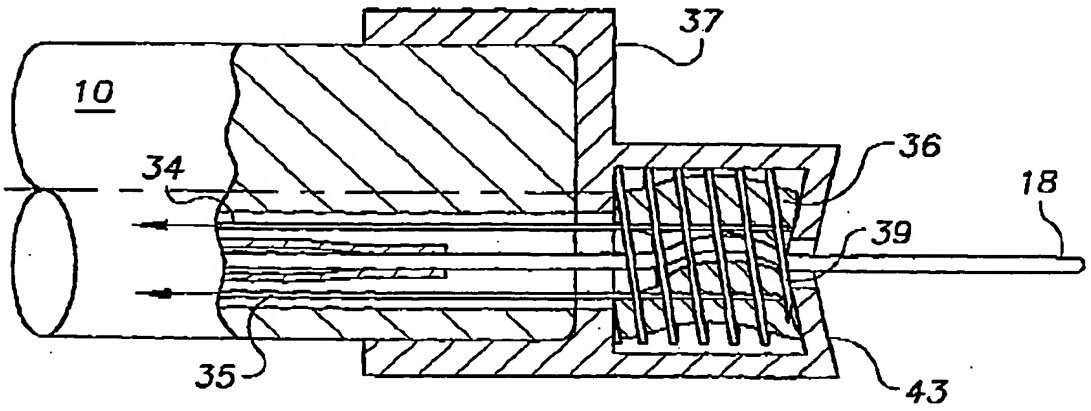

FIG.8A

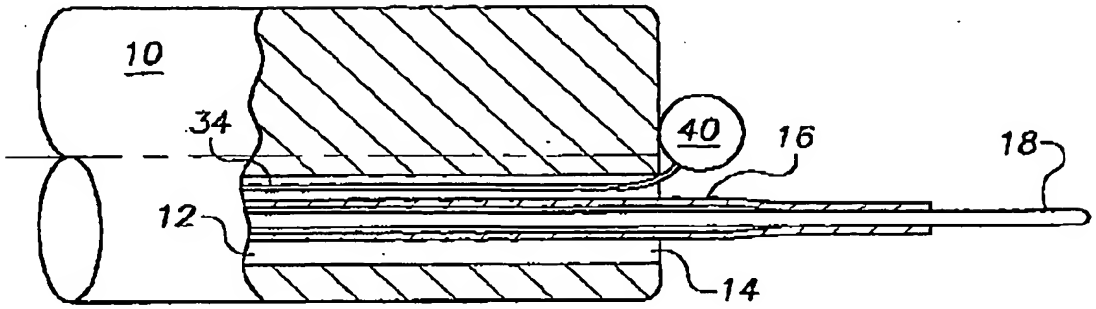

FIG.8B

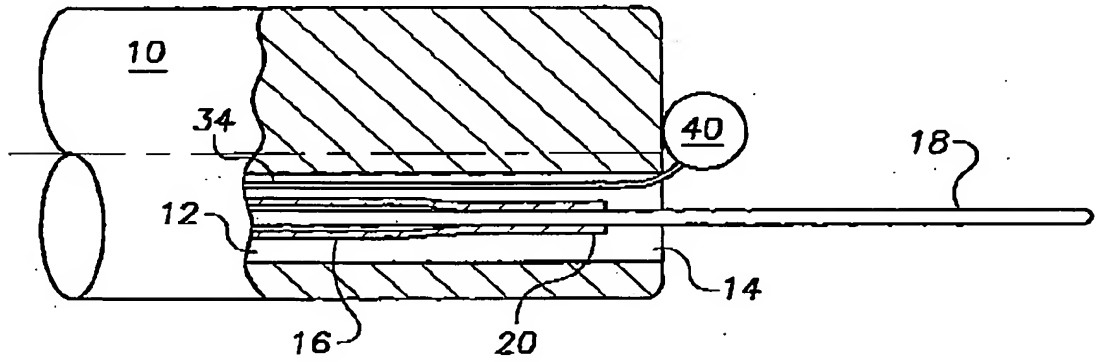

FIG.8C

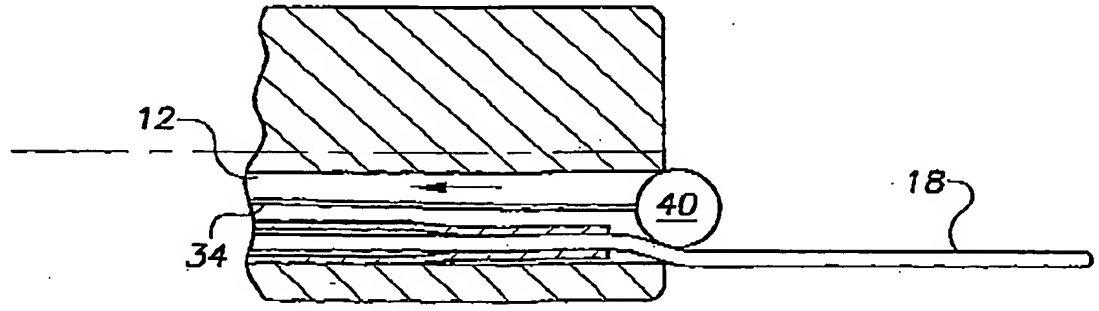

FIG. 9A

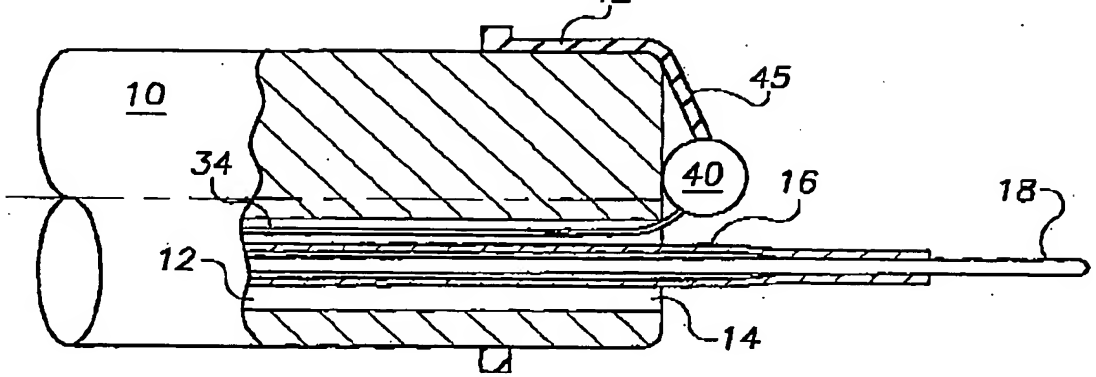

FIG. 9B

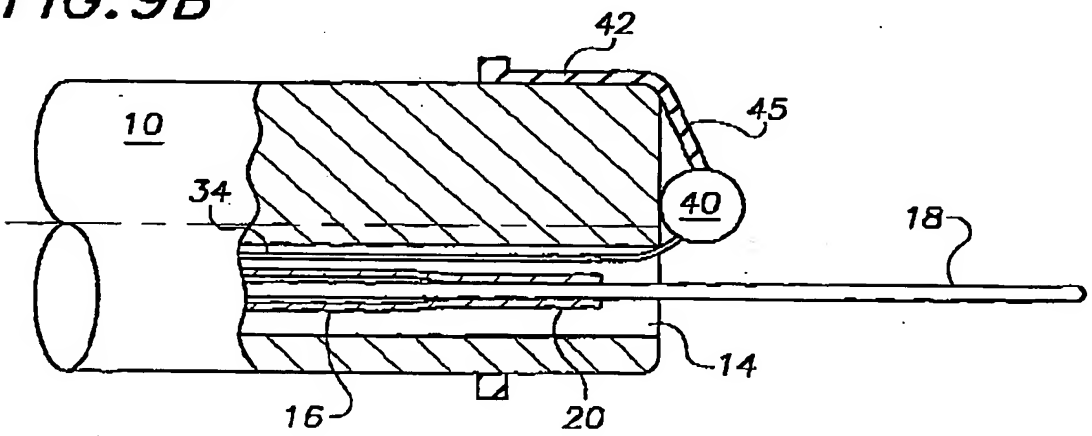

FIG. 9C

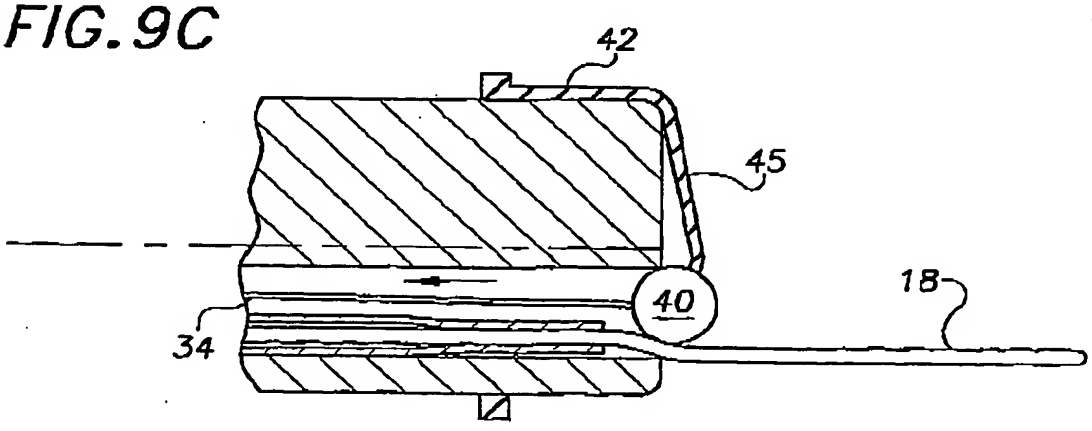

FIG. 10A

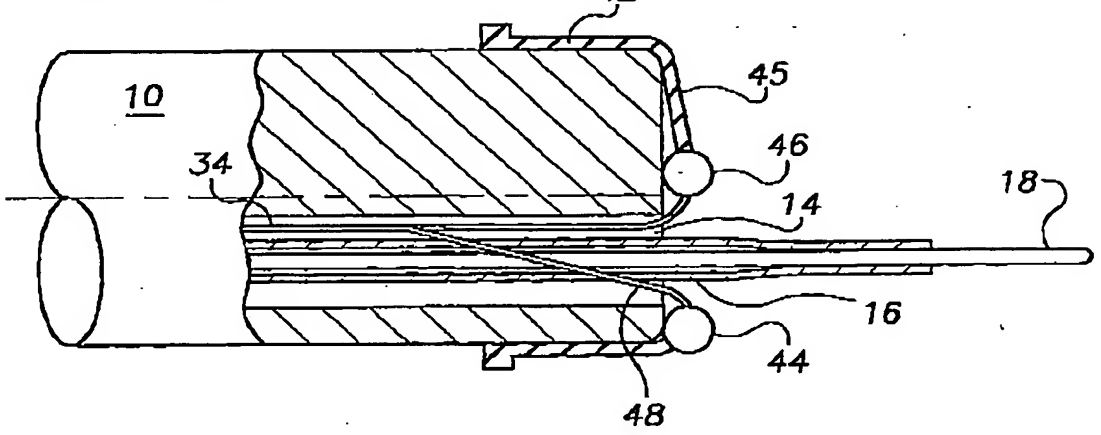

FIG. 10B

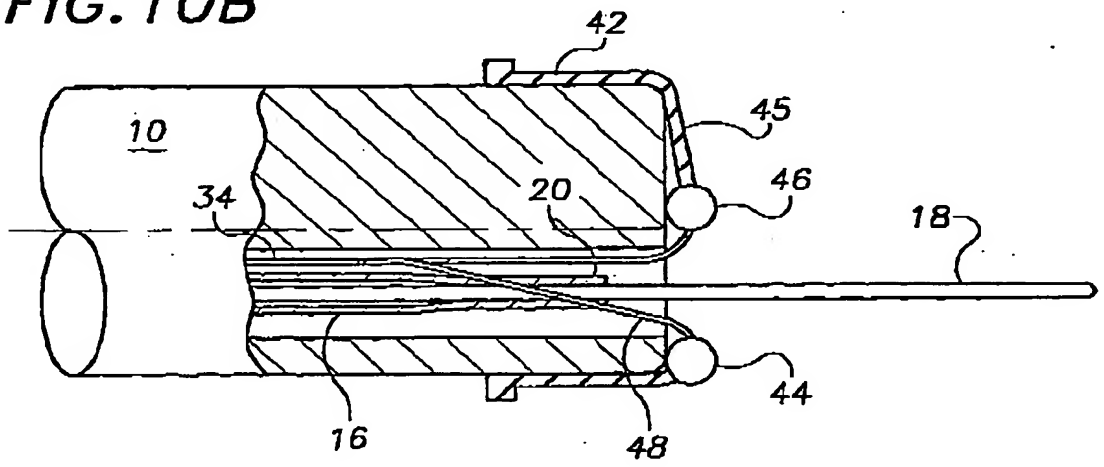

FIG. 10C

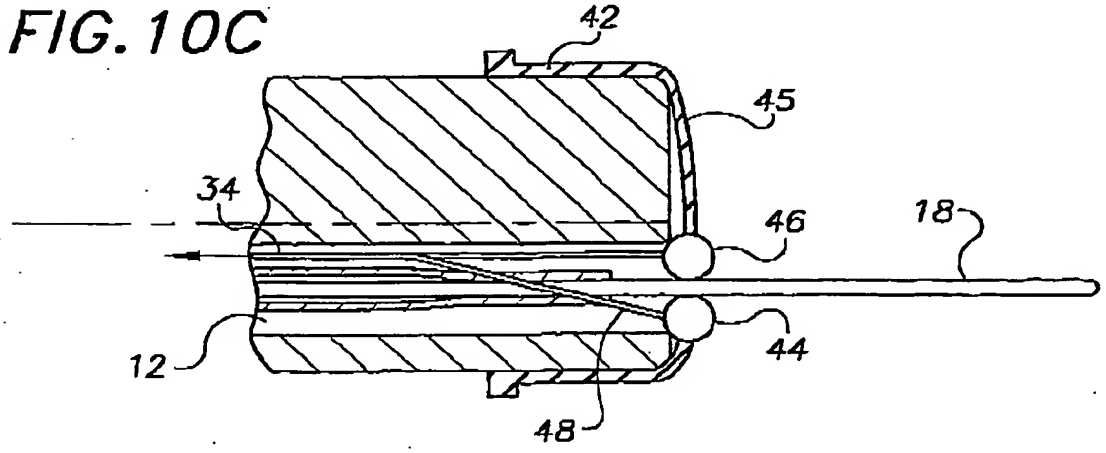

FIG. 11A

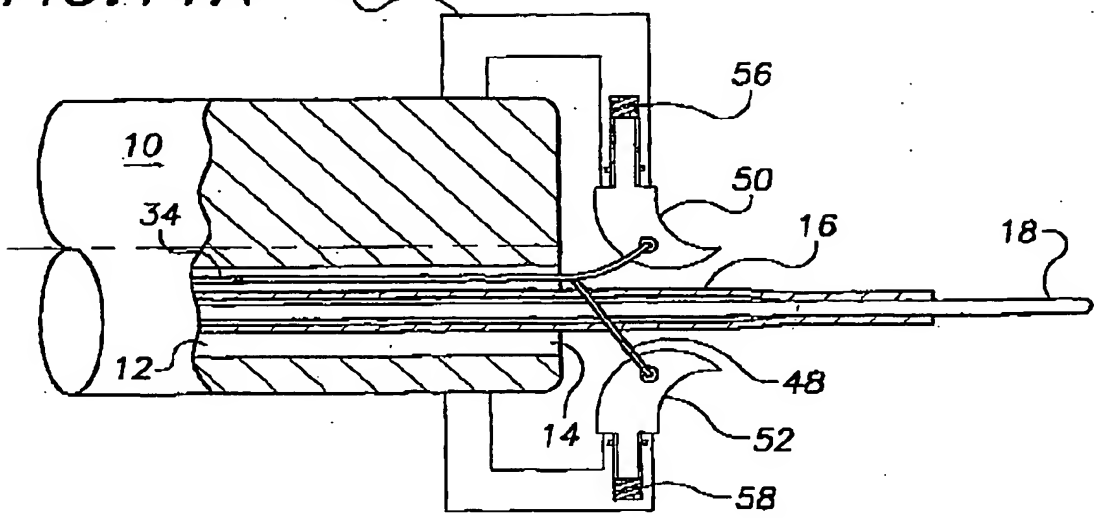

FIG. 11B

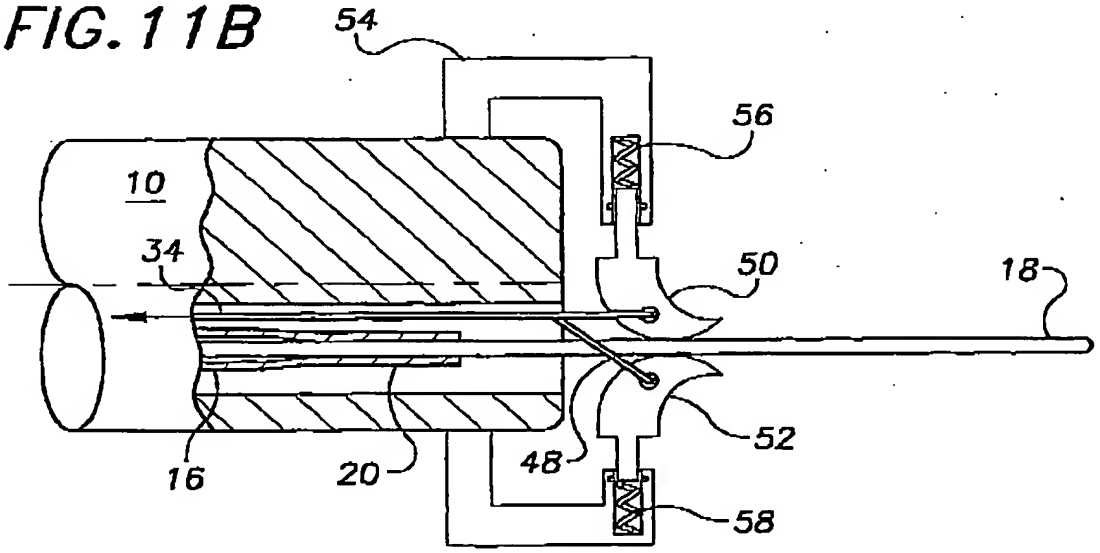

FIG. 11C

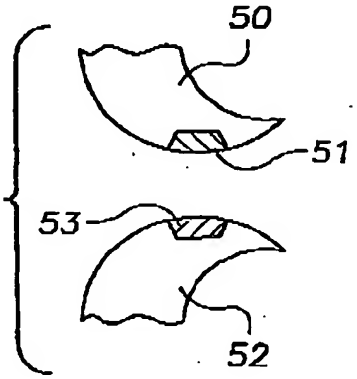

FIG. 12A

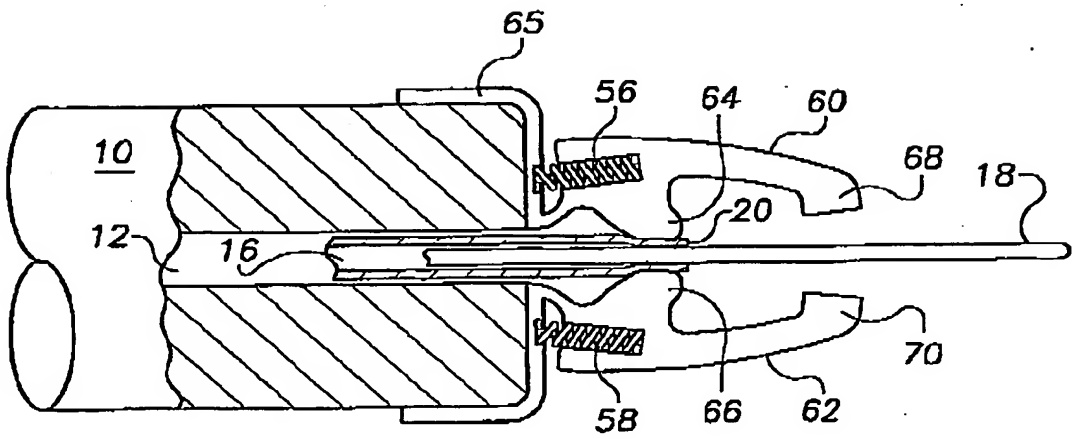

FIG. 12B

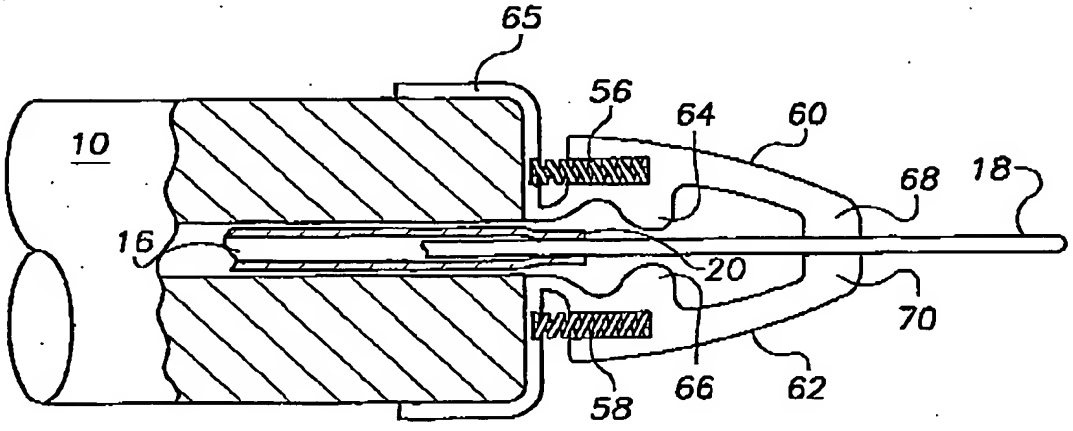

FIG. 13A

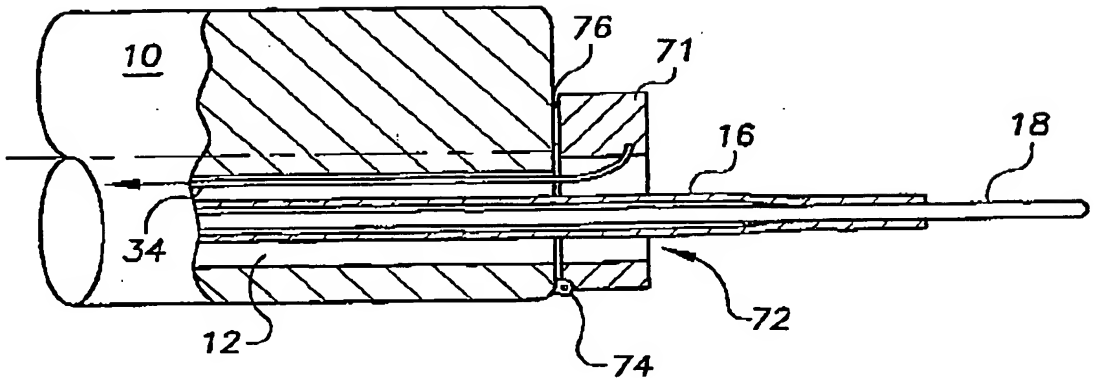

FIG. 13B

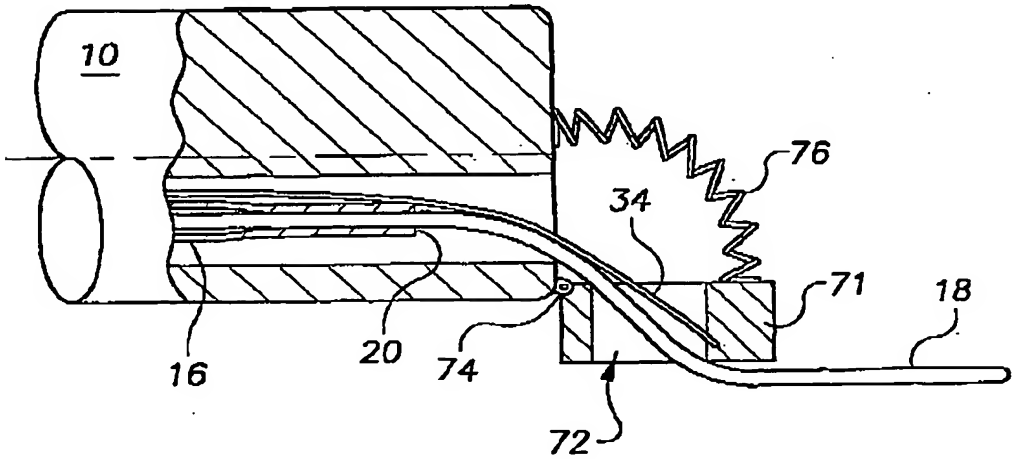

FIG. 14A

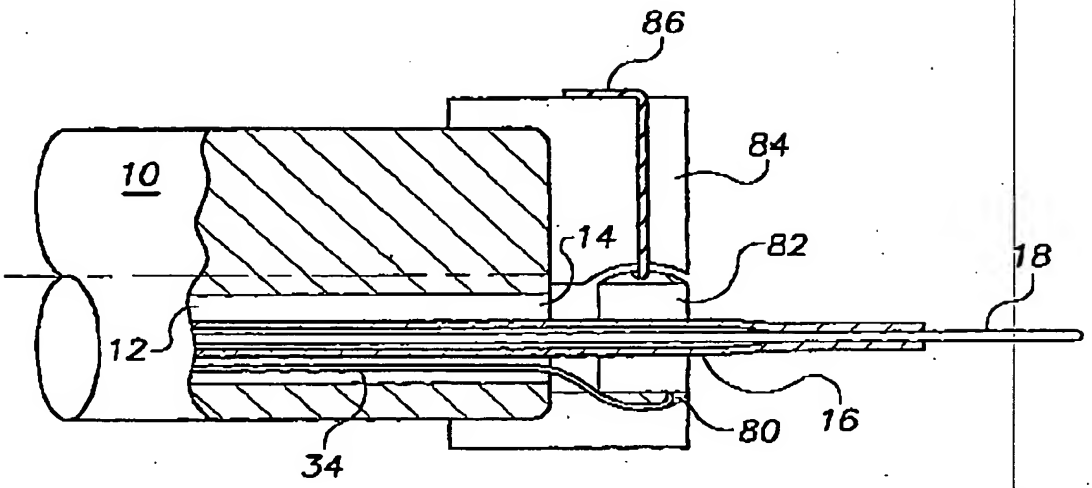

FIG. 14B

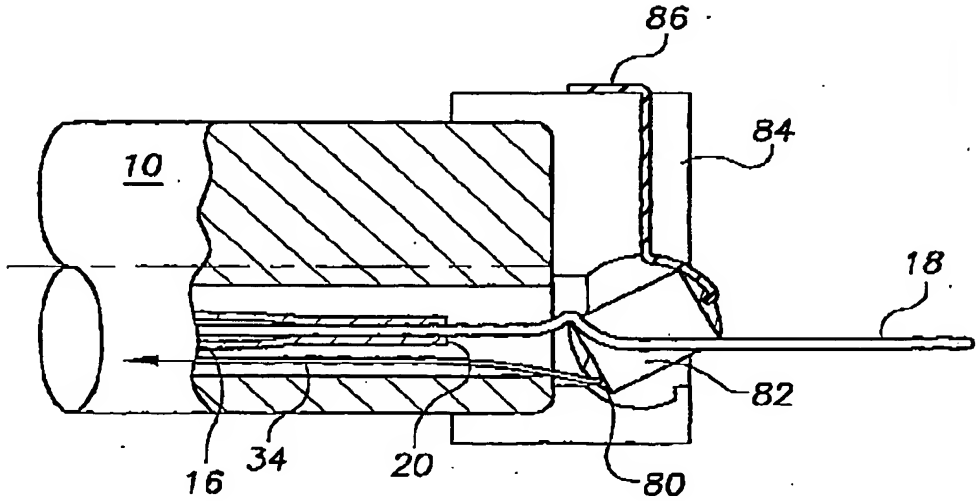

FIG. 15A

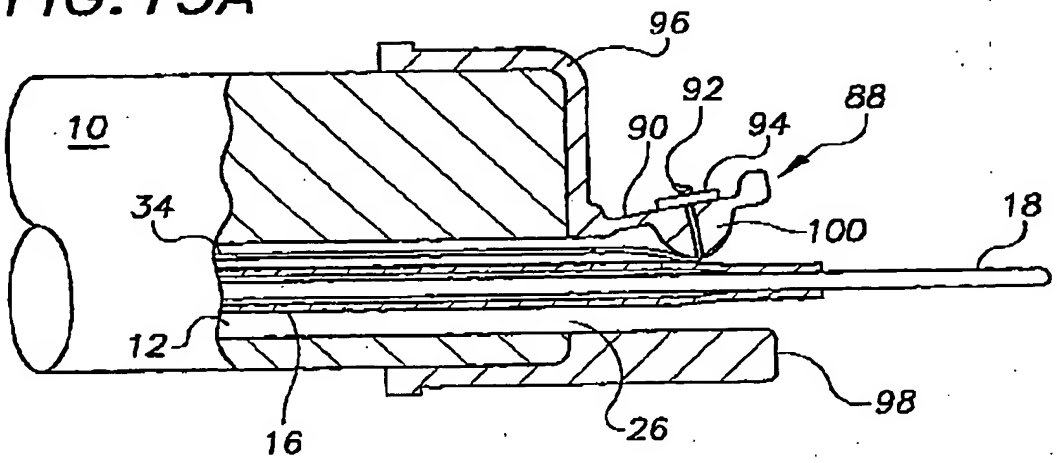

FIG. 15B

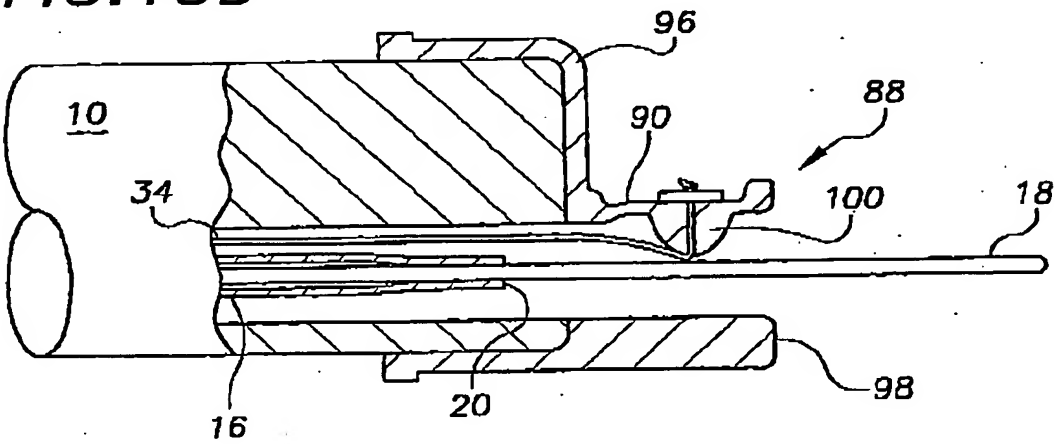

FIG. 15C